SCHEDULE OF PHARMACEUTICAL BENEFITS

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

EFFECTIVE

1 September 2014 - 30 September 2014

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

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PHARMACEUTICAL BENEFITS

These changes to the Schedule of Pharmaceutical Benefits are effective from 1 September 2014. The Schedule is updated on the first day of each month and is available on the Internet at [www.pbs.gov.au](http://www.pbs.gov.au).

## Fees, Patient Contributions and Safety Net Thresholds

The following fees, patient contributions and safety net thresholds apply as at 1 September 2014 and are included, where applicable, in prices published in the Schedule —

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<thead>
<tr>
<th><strong>Dispensing Fees:</strong></th>
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<tbody>
<tr>
<td>Ready-prepared</td>
<td>$6.76</td>
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<td>Dangerous drug fee</td>
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<tr>
<td>Extemporaneously-prepared</td>
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<td>Allowable additional patient charge*</td>
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<th><strong>Additional Fees (for safety net prices):</strong></th>
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<tr>
<td>Ready-prepared</td>
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<td>Extemporaneously-prepared</td>
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<th><strong>Patient Co-payments:</strong></th>
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<td>Concessional</td>
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<td>General</td>
<td>$1421.20</td>
</tr>
<tr>
<td>Concessional</td>
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| **Safety Net Card Issue Fee:** | $9.26 |

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

### Additions

#### Addition – Item

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<tr>
<th>Code</th>
<th>Item</th>
<th>Details</th>
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<tbody>
<tr>
<td>10137M</td>
<td>Cetrotizumab Pegol</td>
<td>Cetrotizumab pegol 200 mg/mL injection, 2 x 1 mL syringes (Cimzia)</td>
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<td>10133H</td>
<td>Everolimus</td>
<td>Everolimus 5 mg tablet, 30 (Afinitor)</td>
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<td>Everolimus</td>
<td>Everolimus 5 mg tablet, 30 (Afinitor)</td>
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<td>Everolimus</td>
<td>Everolimus 10 mg tablet, 30 (Afinitor)</td>
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<tr>
<td>10135K</td>
<td>Everolimus</td>
<td>Everolimus 10 mg tablet, 30 (Afinitor)</td>
</tr>
<tr>
<td>10138N</td>
<td>Ranibizumab</td>
<td>Ranibizumab 1.65 mg/0.165 mL injection, 1 x 0.165 mL syringe (Lucentis)</td>
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#### Addition – Brand

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<td>Amoxicillin AN, EA</td>
<td>Amoxicillin AN, EA – Amoxicillin, amoxicillin 250 mg capsule, 20</td>
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<td>8889W</td>
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<td>Candesartan AN, EA – Candesartan, candesartan cilestil 4 mg tablet, 30</td>
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<td>Candesartan AN, EA</td>
<td>Candesartan AN, EA – Candesartan, candesartan cilestil 8 mg tablet, 30</td>
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<td>8927Q</td>
<td>Candesartan AN, EA</td>
<td>Candesartan AN, EA – Candesartan, candesartan cilestil 16 mg tablet, 30</td>
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<td>Candesartan AN, EA</td>
<td>Candesartan AN, EA – Candesartan, candesartan cilestil 32 mg tablet, 30</td>
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<td>8504N</td>
<td>Candesartan HCTZ AN</td>
<td>Candesartan HCTZ AN 16/12.5, EA – Candesartan + Hydrochlorothiazide, candesartan cilestil 16 mg + hydrochlorothiazide 12.5 mg tablet, 30</td>
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<td>9314F</td>
<td>Candesartan HCTZ AN</td>
<td>Candesartan HCTZ AN 32/12.5, EA – Candesartan + Hydrochlorothiazide, candesartan cilestil 32 mg + hydrochlorothiazide 12.5 mg tablet, 30</td>
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<td>9315G</td>
<td>Candesartan HCTZ AN</td>
<td>Candesartan HCTZ AN 32/25, EA – Candesartan + Hydrochlorothiazide, candesartan cilestil 32 mg + hydrochlorothiazide 25 mg tablet, 30</td>
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<td>8248D</td>
<td>Irbesartan GH, GQ - Irbesartan, irbesartan 300 mg tablet, 30</td>
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<tr>
<td>8404H</td>
<td>Irbesartan HCTZ AN 150/12.5, EA - Irbesartan + Hydrochlorothiazide, irbesartan 150 mg + hydrochlorothiazide 12.5 mg tablet, 30</td>
<td></td>
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<tr>
<td>8404H</td>
<td>Irbesartan HCTZ AN 150/12.5, EA - Irbesartan + Hydrochlorothiazide, irbesartan 150 mg + hydrochlorothiazide 12.5 mg tablet, 30</td>
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<tr>
<td>8405J</td>
<td>Irbesartan HCTZ AN 300/12.5, EA - Irbesartan + Hydrochlorothiazide, irbesartan 300 mg + hydrochlorothiazide 12.5 mg tablet, 30</td>
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<td>1558B</td>
<td>Isosorbide Mononitrate, isosorbide mononitrate 60 mg tablet: modified release, 30 tablets</td>
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<td>25911</td>
<td>Isotretinoin AN, EA - Isotretinoin, isotretinoin 10 mg capsule, 60</td>
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<td>25912</td>
<td>Isotretinoin AN, EA - Isotretinoin, isotretinoin 10 mg capsule, 60</td>
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<td>25924</td>
<td>Isotretinoin AN, EA - Isotretinoin, isotretinoin 20 mg capsule, 60</td>
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<td>25925</td>
<td>Isotretinoin AN, EA - Isotretinoin, isotretinoin 20 mg capsule, 60</td>
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<td>2549E</td>
<td>Isotretinoin AN, EA - Isotretinoin, isotretinoin 40 mg capsule, 30</td>
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<td>Lercanidipine AN, EA - Lercanidipine, lercanidipine hydrochloride 10 mg tablet, 28</td>
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<td>8679T</td>
<td>Lercanidipine AN, EA - Lercanidipine, lercanidipine hydrochloride 20 mg tablet, 28</td>
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<td>8245Y</td>
<td>Letrozolone AN, EA - Letrozolone, letrozolone 2.5 mg tablet, 30</td>
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<td>8654L</td>
<td>Levetiracetam AN, EA - Levetiracetam, levetiracetam 250 mg tablet, 60</td>
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<td>8655M</td>
<td>Levetiracetam AN, EA - Levetiracetam, levetiracetam 500 mg tablet, 60</td>
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<td>8656N</td>
<td>Levetiracetam AN, EA - Levetiracetam, levetiracetam 1 g tablet, 60</td>
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<td>2456G</td>
<td>Lisinopril AN, EA - Lisinopril, lisinopril 5 mg tablet, 30</td>
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<td>2457H</td>
<td>Lisinopril AN, EA - Lisinopril, lisinopril 10 mg tablet, 30</td>
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<td>2458J</td>
<td>Lisinopril AN, EA - Lisinopril, lisinopril 20 mg tablet, 30</td>
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<td>8561N</td>
<td>Meloxicam AN, EA - Meloxicam, meloxicam 7.5 mg tablet, 30</td>
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<td>8562P</td>
<td>Meloxicam AN, EA - Meloxicam, meloxicam 15 mg tablet, 30</td>
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<td>2430X</td>
<td>Metformin AN, EA - Metformin, metformin hydrochloride 500 mg tablet, 100</td>
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<td>1801T</td>
<td>Metformin AN, EA - Metformin, metformin hydrochloride 850 mg tablet, 60</td>
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<td>Metformin AN, EA - Metformin, metformin hydrochloride 1 g tablet, 90</td>
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<td>9365X</td>
<td>Mirtazapine AN, EA - Mirtazapine, mirtazapine 15 mg tablet, 30</td>
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<td>8513C</td>
<td>Mirtazapine AN, EA - Mirtazapine, mirtazapine 30 mg tablet, 30</td>
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<td>8883M</td>
<td>Mirtazapine AN, EA - Mirtazapine, mirtazapine 45 mg tablet, 30</td>
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<td>8855C</td>
<td>Mirtazapine AN ODT, EA - Mirtazapine, MIRTAZAPINE Tablet 15 mg (orally disintegrating), 30</td>
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<td>8856D</td>
<td>Mirtazapine AN ODT, EA - Mirtazapine, MIRTAZAPINE Tablet 30 mg (orally disintegrating), 30</td>
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<td>Mirtazapine AN ODT, EA - Mirtazapine, MIRTAZAPINE Tablet 45 mg (orally disintegrating), 30</td>
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<td>1900B</td>
<td>Moclobemide AN, EA - Moclobemide, moclobemide 150 mg tablet, 60</td>
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<td>Moclobemide AN, EA - Moclobemide, moclobemide 300 mg tablet, 60</td>
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<td>Montelukast AN, EA - Montelukast, montelukast 4 mg tablet: enteric, 30 tablets</td>
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<td>Montelukast AN, EA - Montelukast, montelukast 5 mg tablet: enteric, 28</td>
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<td>3010K</td>
<td>Norfloxacin AN, EA - Norfloxacin, norfloxacin 400 mg tablet, 14</td>
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<td>Olanzapine AN, EA - Olanzapine, olanzapine 2.5 mg tablet, 28</td>
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<td>Olanzapine AN, EA - Olanzapine, olanzapine 5 mg tablet, 28</td>
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<td>8186W</td>
<td>Olanzapine AN, EA - Olanzapine, olanzapine 7.5 mg tablet, 28</td>
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<td>8187X</td>
<td>Olanzapine AN, EA - Olanzapine, olanzapine 10 mg tablet, 28</td>
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<td>Olanzapine AN ODT, EA - Olanzapine, OLANZAPINE Tablet 5 mg (orally disintegrating), 28</td>
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<td>Olanzapine AN ODT, EA - Olanzapine, OLANZAPINE Tablet 10 mg (orally disintegrating), 28</td>
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<td>Olanzapine AN ODT, EA - Olanzapine, olanzapine 15 mg tablet, 28</td>
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<td>8331L</td>
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<td>Ondansetron AN, EA - Ondansetron, ondansetron 4 mg tablet, 4</td>
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<td>Ondansetron AN, EA - Ondansetron, ondansetron 4 mg tablet, 10</td>
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<td>8225X</td>
<td>Ondansetron AN, EA - Ondansetron, ondansetron 8 mg tablet, 4</td>
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<td>1595Y</td>
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<td>Ondansetron AN ODT, EA - Ondansetron, ONDANSETRON Tablet (orally disintegrating) 4 mg, 10</td>
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<td>Pantoprazole AN, EA - Pantoprazole, pantoprazole 40 mg tablet: enteric, 30</td>
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<td>Paroxetine AN, EA - Paroxetine, paroxetine 20 mg tablet, 30</td>
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<td>Pioglitazone AN, EA - Pioglitazone, pioglitazone 15 mg tablet, 28</td>
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<td>8695P</td>
<td>Pioglitazone AN, EA - Pioglitazone, pioglitazone 30 mg tablet, 28</td>
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<td>Pioglitazone AN, EA - Pioglitazone, pioglitazone 45 mg tablet, 28</td>
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<td>2833D</td>
<td>Pravastatin AN, EA - Pravastatin, pravastatin sodium 10 mg tablet, 30</td>
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<td>Pravastatin AN, EA - Pravastatin, pravastatin sodium 10 mg tablet, 30</td>
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<td>Pravastatin AN, EA - Pravastatin, pravastatin sodium 80 mg tablet, 30</td>
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<td>Pravastatin AN, EA - Pravastatin, pravastatin sodium 80 mg tablet, 30</td>
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<td>2893G</td>
<td>Prochlorperazine AN, EA - Prochlorperazine, prochlorperazine maleate 5 mg tablet, 25</td>
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<td>Quetiapine AN, EA - Quetiapine, quetiapine 300 mg tablet, 60</td>
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<td>Rabeprazole AN, EA - Rabeprazole, rabeprazole sodium 10 mg tablet: enteric, 28</td>
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<td>Rabeprazole AN, EA - Rabeprazole, rabeprazole sodium 20 mg tablet: enteric, 30</td>
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<td>Ramipril AN, EA - Ramipril, ramipril 2.5 mg tablet, 30</td>
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<td>1316G</td>
<td>Ramipril AN, EA - Ramipril, ramipril 10 mg tablet, 30</td>
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<td>8470T</td>
<td>Ramipril CH, EA - Ramipril, ramipril 10 mg capsule, 30</td>
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<td>Risedronate AN, EA - Risedronate, risedronate sodium 35 mg tablet, 4</td>
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<td>8787L</td>
<td>Risperidone AN, EA - Risperidone, risperidone 500 microgram tablet, 60</td>
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<td>Risperidone AN, EA - Risperidone, risperidone 1 mg tablet, 60</td>
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<td>3169T</td>
<td>Risperidone AN, EA - Risperidone, risperidone 1 mg tablet, 60</td>
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</table>
injection, 1 x 500 mL bag
chloride 0.6% (3 g/500 mL) + potassium chloride 0.04% (200 mg/500 mL) + calcium chloride dihydrate 0.027% (135 mg/500 mL)

Lactate + Sodium Chloride + Potassium Chloride + Calcium Chloride Dihydrate

Glucose Indicator Blood

Deletions

Deletion – Item

9416N Glucose, glucose 5% (12.5 g/250 mL) injection, 1 x 250 mL bag (Glucose 5% Freeflex)
9405K Glucose, glucose 5% (25 g/500 mL) injection, 1 x 500 mL bag (Fresenius Kabi Australia Pty Limited)
9444C Glucose, glucose 5% (25 g/500 mL) injection, 1 x 500 mL bag (Fresenius Kabi Australia Pty Limited)
9445D Glucose, glucose 10% (50 g/500 mL) injection, 1 x 500 mL bag (Fresenius Kabi Australia Pty Limited)
9013J Glucose Indicator Blood, glucose indicator blood strip: diagnostic, 50 (Glucocard 01 Sensor)
9251K Glucose Indicator Blood, glucose indicator blood strip: diagnostic, 50 (Glucocard 01 Sensor)
9416N Lactate + Sodium Chloride + Potassium Chloride + Calcium Chloride Dihydrate, lactate sodium 0.322% (1.61 g/500 mL) + sodium chloride 0.6% (3 g/500 mL) + potassium chloride 0.04% (200 mg/500 mL) + calcium chloride dihydrate 0.027% (135 mg/500 mL) injection, 1 x 500 mL bag (Fresenius Kabi Australia Pty Limited)
The following items will be deleted from the Schedule of Pharmaceutical Benefits on 1 October 2014:

- **Advance Notices – Deletion of Brand**
  - Carbamazepine 100 mg tablet, 200 (Carbamazepine Sandoz)
  - Carbamazepine 100 mg tablet, 200 (Carbamazepine Sandoz)

The following item will be deleted from the Schedule of Pharmaceutical Benefits on 1 November 2014:

- **Advance Notices – Deletion of Item**
  - Carbamazepine 100 mg tablet, 200 (Carbamazepine Sandoz)

The restrictions relating to ankylosing spondylitis for the following items have been amended to include reference to certolizumab pegol

- **Alteration – Restriction**
  - Ranibizumab, ranibizumab 2.3 mg/0.23 mL injection, 1 x 0.23 mL vial (Lucentis)

The following items will be deleted from the Schedule of Pharmaceutical Benefits on 1 October 2014:

- **Deletion – Brand**
  - Carbamazepine, carbamazepine 20 mg capsule [14 capsules] (&) clarithromycin 500 mg tablet [14 tablets] (&) amoxycillin 500 mg capsule [28 capsules], 1 pack (Probiot Hp7)
  - Oxprenolol, oxprenolol hydrochloride 20 mg tablet, 100 (Corbeton 20)
  - Sodium Chloride, sodium chloride 0.9% (2.25 g/500 mL) injection, 1 x 500 mL (Fresenius Kabi Australia Pty Limited)

The following items will be deleted from the Schedule of Pharmaceutical Benefits on 1 October 2014:

- **Advance Notices – Deletion of Item**
  - Carbamazepine 100 mg tablet, 200 (Carbamazepine Sandoz)

**Advance Notices**

**Advance Notices – Deletion of Item**
The following items will be deleted from the Schedule of Pharmaceutical Benefits on 1 October 2014:

- **1708X** Carbamazepine, carbamazepine 100 mg tablet, 200 (Carbamazepine Sandoz)
- **1755J** Carbamazepine, carbamazepine 100 mg tablet, 200 (Carbamazepine Sandoz)
- **5559N** Polyethylene Glycol-400, polyethylene glycol-400 0.25% eye drops, 15 mL (Blink Intensive Tears)
- **9491M** Polyethylene Glycol-400, polyethylene glycol-400 0.25% eye drops, 15 mL (Blink Intensive Tears)
- **9492N** Polyethylene Glycol-400, polyethylene glycol-400 0.25% eye drops, 15 mL (Blink Intensive Tears)
- **5560P** Polyethylene Glycol-400, polyethylene glycol-400 0.25% eye drops, 20 x 0.4 mL unit doses (Blink Intensive Tears)
- **9493P** Polyethylene Glycol-400, polyethylene glycol-400 0.25% eye drops, 20 x 0.4 mL unit doses (Blink Intensive Tears)

The following item will be deleted from the Schedule of Pharmaceutical Benefits on 1 November 2014:

- **2776D** Ethinylestradiol + Norethisterone, ethinylestradiol 35 microgram + norethisterone 500 microgram tablet [48] (&) ethinylestradiol 35 microgram + norethisterone 1 mg tablet [36] (&) inert substance tablet [28], 112 [4 x 28] (Improvil 28 Day)

**Advance Notices – Deletion of Brand**
The following items will be deleted from the Schedule of Pharmaceutical Benefits on 1 October 2014:

- **1628Q** Tolvon, MK – Mianserin, mianserin hydrochloride 20 mg tablet, 50
- **2419H** Carbamazepine Sandoz, SZ – Carbamazepine, carbamazepine 200 mg tablet, 200
- **5040G** Carbamazepine Sandoz, SZ – Carbamazepine, carbamazepine 200 mg tablet, 200
SECTION 100 – HIGHLY SPECIALISED DRUGS PROGRAM

Additions

Addition – Item
10136L Macitentan, macitentan 10mg tablet, 30 (Opsumit) (Public)
10134J Macitentan, macitentan 10mg tablet, 30 (Opsumit) (Private)

Deletions

Deletion – Item
5821J Darunavir, darunavir 400 mg tablet, 60 (Prezista) (Public)
5823L Darunavir, darunavir 400 mg tablet, 60 (Prezista) (Private)

Alterations

Alteration – Restriction
5607D Ambrisentan, ambrisentan 5 mg tablet, 30 (Volibris)(Public)
9648T Ambrisentan, ambrisentan 5 mg tablet, 30 (Volibris)(Private)
5608E Ambrisentan, ambrisentan 10 mg tablet, 30 (Volibris)(Public)
9649W Ambrisentan, ambrisentan 10 mg tablet, 30 (Volibris)(Private)
5618Q Bosentan, bosentan 62.5 mg tablet, 60 (Tracleer)(Public)
6429J Bosentan, bosentan 62.5 mg tablet, 60 (Tracleer)(Private)
5619R Bosentan, bosentan 125 mg tablet, 60 (Tracleer)(Public)
6430K Bosentan, bosentan 125 mg tablet, 60 (Tracleer)(Private)
10130E Epoprostenol, epoprostenol 500 microgram injection, 1 x 500 microgram vial (Veletri)(Public)
10111E Epoprostenol, epoprostenol 500 microgram injection, 1 x 500 microgram vial (Veletri)(Private)
10117L Epoprostenol, epoprostenol 1.5 mg injection, 1 x 1.5 mg vial (Veletri)(Public)
10129D Epoprostenol, epoprostenol 1.5 mg injection, 1 x 1.5 mg vial (Veletri)(Private)
5030R Epoprostenol, EPOPROSTENOL SODIUM Powder for I.V. infusion 500 micrograms (base) infusion administration set, 1 (Flolan Kit)(Public)
5036C Epoprostenol, EPOPROSTENOL SODIUM Powder for I.V. infusion 500 micrograms (base) infusion administration set, 1 (Flolan Kit)(Private)
5035B Epoprostenol, EPOPROSTENOL SODIUM Powder for I.V. infusion 1.5 mg (base) infusion administration set, 1 (Flolan Kit)(Public)
5042J Epoprostenol, EPOPROSTENOL SODIUM Powder for I.V. infusion 1.5 mg (base) infusion administration set, 1 (Flolan Kit)(Private)
5751Q Iloprost, iloprost 20 microgram/2 mL inhalation: solution, 30 x 2 mL ampoules (Ventavis)(Public)
6456T Iloprost, iloprost 20 microgram/2 mL inhalation: solution, 30 x 2 mL ampoules (Ventavis)(Private)
9547L Sildenafil, sildenafil 20 mg tablet, 90 (APO-Sildenafil PHT, Revatio, Sildenafil Sandoz PHT 20)(Public)
9605M Sildenafil, sildenafil 20 mg tablet, 90 (APO-Sildenafil PHT, Revatio, Sildenafil Sandoz PHT 20)(Private)
1308W Tadalafil, tadalafil 20 mg tablet, 56 (Adcirca)(Public)
1304P Tadalafil, tadalafil 20 mg tablet, 56 (Adcirca)(Private)

The restrictions relating to ankylosing spondylitis for the following items have been amended to include reference to certolizumab pegol
5753T Infliximab, infliximab 100 mg injection, 1 x 100 mg vial (Remicade) (Public)
6448J Infliximab, infliximab 100 mg injection, 1 x 100 mg vial (Remicade)(Private)
Addresses — Department of Human Services

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

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

**New South Wales and Australian Capital Territory**

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

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

**Western Australia**

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

**South Australia and Northern Territory**

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

**Tasmania**

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

**Queensland**

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

**National Program Management**

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

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

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

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

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

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

For telephone applications please have the following information available:

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

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

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

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

Requests for Drugs via the Special Access Scheme (SAS)

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

Department of Veterans’ Affairs

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

Telephone Interpreter Service

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

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

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

<table>
<thead>
<tr>
<th>State</th>
<th>Address</th>
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<tr>
<td>NSW</td>
<td>The New Children’s Hospital</td>
<td>131 126</td>
</tr>
<tr>
<td></td>
<td>Hawkesbury Road</td>
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</tr>
<tr>
<td></td>
<td>Westmead NSW 2148</td>
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<tr>
<td></td>
<td>Tel: (02) 9845 3111</td>
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<tr>
<td>VIC</td>
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<tr>
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<td></td>
<td>Heidelberg VIC 3084</td>
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<tr>
<td></td>
<td>Tel: (03) 9496 4410</td>
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<td><a href="http://www.austin.org.au/poisons">www.austin.org.au/poisons</a></td>
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<tr>
<td>QLD</td>
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<tr>
<td>WA</td>
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<td>131 126</td>
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<tr>
<td>QLD</td>
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<tr>
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<tr>
<td></td>
<td>Tel: (07) 3636 7098</td>
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<td>(07) 3636 7599</td>
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<tr>
<td>SA</td>
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<tr>
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<td></td>
<td>Adelaide SA 5000</td>
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<tr>
<td></td>
<td>Tel: (08) 8222 5546</td>
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<tr>
<td></td>
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<tr>
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<tr>
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<tr>
<td></td>
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<tr>
<td></td>
<td>Hobart Tas 7001</td>
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<td></td>
<td>Tel: (03) 6222 8737</td>
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<tr>
<td></td>
<td>Royal Darwin Hospital</td>
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<tr>
<td></td>
<td>PO Box 41326</td>
<td></td>
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<tr>
<td></td>
<td>Casuarina NT 0811</td>
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<tr>
<td></td>
<td>Tel: (08) 8922 8424</td>
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<tr>
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</tr>
<tr>
<td></td>
<td>Canberra Hospital</td>
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</tr>
<tr>
<td></td>
<td>Yamba Drive</td>
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<tr>
<td></td>
<td>Garran ACT 2605</td>
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<tr>
<td></td>
<td>Tel: (02) 6244 3333</td>
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List of Contact Officers for Recalls of Therapeutic Goods

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

These officers may be contacted —

- to obtain information about current recalls
- to report suspected problems relating to the quality, safety or efficacy of a therapeutic good

Australian Recall Coordinator

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

Australian Capital Territory

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

New South Wales

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

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

Victoria

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

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

Queensland

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

Mr A. Hawkins
Bh 07 3328 9310
Mobile 0449 267 625
Fax 07 3228 9354
E-mail andrew_hawkins@health.qld.gov.au

South Australia

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

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

Western Australia

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

Tasmania

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

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

Northern Territory

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

Mr T. DeZilva
Bh 08 8922 7340
Mobile 0400 251 419
Fax 08 8922 7200
E-mail tyronne.dezilva@nt.gov.au
<table>
<thead>
<tr>
<th>Code</th>
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</table>
| AB   | Abbott Australasia Pty Ltd  
|      | Sir Joseph Banks Corporate Park  
|      | 32-34 Lord Street  
|      | BOTANY NSW 2019  
|      | Tel: 1800 801 478 |
| AE   | AFT Pharmaceuticals Pty Ltd  
|      | Level 1  
|      | 296 Burns Bay Road  
|      | LANE COVE NSW 2066  
|      | Tel: 1800 097 639 |
| AF   | Alphapharm Pty Ltd  
|      | Level 1  
|      | 30 The Bond, 30-34 Hickson Rd  
|      | MILLERS POINT NSW 2000  
|      | Tel: 1800 028 365 |
| AG   | Allergan Australia Pty Limited  
|      | Level 4  
|      | 810 Pacific Highway  
|      | Gordon NSW 2072  
|      | Tel: 1800 252 224 |
| AL   | Alphapharm Pty Ltd  
|      | Level 1  
|      | 30 The Bond, 30-34 Hickson Rd  
|      | MILLERS POINT NSW 2000  
|      | Tel: 1800 028 365 |
| AN   | Amgen Australia Pty Limited  
|      | Avaya House  
|      | Level 7, 123 Epping Road  
|      | NORTH SYDE NSW 2113  
|      | Tel: 1800 803 638 |
| AO   | AMO Australia Pty Limited  
|      | Level 3, Building 2  
|      | 20 Bridge Street  
|      | PYMBLE NSW 2073  
|      | Tel: 1800266111 |
| AP   | AstraZeneca Pty Ltd  
|      | Alma Road  
|      | NORTH SYDE NSW 2113  
|      | Tel: 1800 805 342 |
| AQ   | Alcon Laboratories (Australia) Pty Ltd  
|      | 10/25 Frenchs Forest Road East  
|      | FRENCHS FOREST NSW 2086  
|      | Tel: 1800 025 032 |
| AS   | Aspen Pharmacare Australia Pty Limited  
|      | 34-36 Chandos Street  
|      | ST LEONARDS NSW 2065  
|      | Tel: (02) 8436 8300 |
| AT   | Actelion Pharmaceuticals Australia Pty Ltd  
|      | Suite 6  
|      | 13b Narabang Way  
|      | Belrose NSW 2085  
|      | Tel: (02) 9486 4600 |
| AV   | sanofi-aventis Australia Pty Ltd  
|      | Building D, Talavera Corporate Centre  
|      | 12-24 Talavera Road  
|      | MACQUARIE PARK NSW 2113  
|      | Tel: +61 (0) 2 8666 2000 |

<table>
<thead>
<tr>
<th>Code</th>
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</table>
| BB   | Blackmores Limited  
|      | 20 Jubilee Avenue  
|      | Warriewood NSW 2102  
|      | Tel: +61 (0) 2 9910 5000  
|      | Fax: +61 (0) 2 9910 5555 |
| BD   | Biogen Idec Australia Pty Ltd  
|      | Suite 1, Level 5  
|      | 123 Epping Road  
|      | NORTH SYDE NSW 2113  
|      | Tel: +61 (0) 2 8875 3900 |
| BE   | Beiersdorf Australia Ltd  
|      | 4 Khartoum Road  
|      | NORTH SYDE NSW 2113  
|      | Tel: +61 (0) 2 9888 0977  
|      | Fax: +61 (0) 2 9887 3487 |
| BG   | Sandoz Pty Ltd  
|      | Suite 201, Level 2  
|      | 19 Harris Street  
|      | Pyrmont NSW 2009  
|      | Tel: 1800 726 369 |
| BI   | Biotech Pharmaceuticals Pty Ltd  
|      | 83 Cherry Lane  
|      | LAVERTON NORTH VIC 3026  
|      | Tel: (03) 9278 7555 |
| BN   | Bayer Australia Ltd  
|      | 875 Pacific Highway  
|      | PYMBLE NSW 2041  
|      | Tel: 1800 673 270 |
| BQ   | Bristol-Myers Squibb Australia Pty Ltd  
|      | Level 2  
|      | 4 Nexus Court  
|      | Mulgrave VIC 3170  
|      | Tel: 1800 067 567 |
| BR   | B. Braun Australia Pty Ltd  
|      | Norwest Business Park  
|      | 17 Lexington Drive  
|      | BELLA VISTA NSW 2153  
|      | Tel: +61 (0) 2 9629 0200 |
| BU   | Bausch & Lomb (Australia) Pty Ltd  
|      | Ground Floor  
|      | 16 Giffnock Avenue  
|      | MACQUARIE PARK NSW 2113  
|      | Tel: (02) 9887 1444 |
| BV   | B.S.N.  
|      | 315 Ferntree Gully Road  
|      | Mount Waverley VIC 3149  
|      | Tel: +61 (0) 3 8540 6777 |
| BX   | Baxter Healthcare Pty Limited  
|      | 1 Baxter Drive  
|      | OLD TOONGABBIE NSW 2146  
|      | Tel: 1300 789 646 |
| BY   | Boehringer Ingelheim Pty Ltd  
|      | 78 Waterloo Road  
|      | NORTH SYDE NSW 2113  
<p>|      | Tel: (02) 8875 8600 |</p>
<table>
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| BZ   | Boucher & Muir Pty Ltd  
Level 1, 134 Willoughby Road  
Crows Nest NSW 2065  
Tel: 1800 627 680 |
| CC   | ConvaTec A Division of Bristol-Myers Squibb Australia Pty Ltd  
606 Hawthorn Road  
East Brighton VIC 3187  
Tel: 1800 335 276 |
| CH   | Apotex Pty Ltd  
16 Giffnock Avenue  
MACQUARIE PARK NSW 2113  
Tel: 1800 276 839 |
| CJ   | Celgene Pty Limited  
Level 7  
607 St Kilda Road  
MELBOURNE VIC 3044  
Tel: (03) 9539 5500 |
| CR   | Pharmacor Pty Limited  
Suite 401  
7 Oaks Avenue  
DeeWhy NSW 2099  
Tel: 1300 138 805 |
| CS   | bioCSL (Australia) Pty Ltd  
63 Poplar Road  
Parkville VIC 3052  
Tel: 1800 008 275 |
| CT   | Coloplast Pty Ltd  
33 Gilby Road  
Mount Waverley VIC 3149  
Tel: 1800 673 317 |
| CU   | Care Pharmaceuticals Pty Limited  
Suite 303, Level 3, 59-75 Grafton Street  
Bondi Junction NSW 2022  
Tel: 1800 788 870 |
| CX   | Contact Lens Centre Australia Limited  
Unit D6, Hallmarc Business Park  
Cnr Westall and Centre Roads  
CLAYTON VIC 3168  
Tel: (03) 9543 1811 |
| DO   | Aurobindo Pharma (Australia) Pty Limited  
Unit 3 North RydeLink Business Park  
277-283 Lane Cove Road  
Macquarie Park NSW 2113  
Tel: +61 (0)2 9805 6000 |
| DQ   | Church & Dwight (Australia) Pty Ltd  
Unit 1/108 Old Pittwater Road  
Brookvale NSW 2100  
Tel: 1800 222 099 |
| DV   | Medical Developments International Limited  
6/56 Smith Road  
SPRINGVALE VIC 3171  
Tel: (03) 9547 1888 |
| EA   | Amneal Pharmaceuticals Pty Ltd  
12 River Street  
South Yarra VIC 3141  
Tel: +61 (0)3 8849 1200  
Fax: +61 (0)3 8849 1299 |
| EH   | Entra Health Systems Pty Ltd  
12/60 Castlereagh Street  
SYDNEY NSW 2000  
Tel: (02) 9846 6642 |
| EL   | Eli Lilly Australia Pty Ltd  
112 Wharf Road  
West Ryde NSW 2114  
Tel: (02) 9325 4444 |
| EO   | Ego Pharmaceuticals Proprietary Limited  
21-31 Malcolm Road  
Braeside VIC 3195  
Tel: (03) 9587 1088 |
| ER   | Eris Pharmaceuticals (Australia) Pty Ltd  
6 Eastern Road  
South Melbourne VIC 3205  
Tel: +61 (0)3 9690 8473  
Fax: +61 (0)3 9690 8479 |
| EU   | Emerge Health Pty Ltd  
Suite 3, Level 1  
2 Theatre Place  
Canterbury VIC 3126  
Tel: +61 (0)3 9077 4486  
Fax: +61 (0)3 8672 0792 |
| FB   | Pierre Fabre Medicament Australia Pty Ltd  
Unit 3B  
1 Richardson Place  
NORTH RYDE NSW 2113  
Tel: +61 (0)2 8662 9800 |
| FI   | Boehringer Ingelheim Pty Ltd  
78 Waterloo Road  
NORTH RYDE NSW 2113  
Tel: (02) 8875 8600 |
| FK   | A. Menarini Australia Pty Limited  
Level 8  
67 Albert Avenue  
Chatswood NSW 2067  
Tel: +61 (0)2 9080 7200 |
| FM   | Fawns and McAllan Proprietary Limited  
34-36 Chandos Street  
ST LEONARDS NSW 2065  
Tel: +61 (0)2 8436 8300 |
| FP   | Ferring Pharmaceuticals Pty Limited  
Suite 2, Level 1, Building 1  
Pymble Corporate Centre  
PYMBLE NSW 2073  
Tel: +61 (0)2 9497 2300  
Fax: +61 (0)2 9497 2399 |
| FR   | Merck Sharp & Dohme (Australia) Pty Ltd  
Level 1, Building A  
26 Talavera Road  
MACQUARIE PARK NSW 2113  
Tel: +61 (0)2 8988 8000 |
| FZ   | Pfizer Australia Pty Ltd  
38-42 Wharf Road  
WEST RYDE NSW 2114  
Tel: +61 (0)2 9850 3333 |
## Index of Manufacturers' codes

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<thead>
<tr>
<th>Code</th>
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<th>Telephone</th>
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<tr>
<td>GA</td>
<td>Galderma Australia Pty Ltd</td>
<td>Suite 4, 138 Narabang Way, BELROSE NSW 2085</td>
<td>(02) 9479 0600</td>
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<tr>
<td>GC</td>
<td>GlaxoSmithKline Australia Pty Ltd</td>
<td>Level 4, 436-438 Johnston Street, Abbotsford VIC 3067</td>
<td>(03) 9721 8600</td>
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<tr>
<td>GH</td>
<td>Mercury Pharma (Australia) Pty Limited</td>
<td>Level 1, 134 Willoughby Road, Crows Nest NSW 2065</td>
<td>(02) 9431 6333</td>
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<td>GI</td>
<td>Gilead Sciences Pty Limited</td>
<td>Level 1, 128 Jollimont Road, EAST MELBOURNE VIC 3002</td>
<td>(03) 9272 4400</td>
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<tr>
<td>GK</td>
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<td>(03) 9721 8600</td>
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<td>GN</td>
<td>Actavis Pty Ltd</td>
<td>Level 5, 117 Harrington Street, The Rocks NSW 2000</td>
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<td>GQ</td>
<td>Generic Health Pty Ltd</td>
<td>Level 1, 1100-1102 Toorak Road, CAMBERWELL VIC 3124</td>
<td>(03) 9809 7900</td>
<td>(03) 9809 7999</td>
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<td>GX</td>
<td>Apotex Pty Ltd</td>
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<td>GZ</td>
<td>sanofi-aventis Australia Pty Ltd</td>
<td>Building D, Talavera Corporate Centre 12-24 Talavera Road, MACQUARIE PARK NSW 2113</td>
<td>(02) 8666 2000</td>
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<td>HH</td>
<td>Hospira Pty Limited</td>
<td>Level 3, 500 Collins Street, MELBOURNE VIC 3000</td>
<td>1300 046 774</td>
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<td>HL</td>
<td>Helex-A Pty. Ltd.</td>
<td>9/7 Finella Avenue, CASTLE HILL NSW 2154</td>
<td>1800 824 166</td>
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<tr>
<td>HM</td>
<td>Meda Pharmaceuticals Pty Ltd</td>
<td>Suite 1, Level 3, 110 Pacific Highway, St Leonards NSW 2065</td>
<td>(02) 8209 3422</td>
<td>(02) 9436 4489</td>
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<tr>
<td>HR</td>
<td>Paul Hartmann Pty Ltd</td>
<td>27-28/11-21 Underwood Road, Homebush NSW 2140</td>
<td>1800 805 839</td>
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<td>HX</td>
<td>Sandoz Pty Ltd</td>
<td>Suite 201, Level 2, 19 Harris Street, Pyrmont NSW 2009</td>
<td>1800 726 369</td>
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<tr>
<td>IA</td>
<td>iNova Pharmaceuticals (Australia) Pty Limited</td>
<td>Po Box 5033, WEST CHATSWOOD NSW 2067</td>
<td>(02) 8918 6415</td>
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<tr>
<td>IK</td>
<td>Medtronic Australasia Pty Ltd</td>
<td>97 Waterloo Road, North Ryde NSW 2113</td>
<td>(02) 9857 9000</td>
<td></td>
</tr>
<tr>
<td>IQ</td>
<td>Alcon Laboratories (Australia) Pty Ltd</td>
<td>10/25 Frenchs Forest Road East, FRENCHS FOREST NSW 2086</td>
<td>1800 025 032</td>
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<tr>
<td>IS</td>
<td>Ipsen Pty Ltd</td>
<td>Level 2, Building 4, Brandon Office Park, GLEN WAVERLEY VIC 3150</td>
<td>(03) 8544 8100</td>
<td></td>
</tr>
<tr>
<td>IV</td>
<td>iNova Pharmaceuticals (Australia) Pty Limited</td>
<td>Po Box 5033, WEST CHATSWOOD NSW 2067</td>
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<td>JC</td>
<td>Janssen-Cilag Pty Ltd</td>
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<td>Johnson &amp; Johnson Medical Pty Ltd</td>
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Tel: 1800 801 478 |
| KP   | Eli Lilly Australia Pty Ltd  
112 Wharf Road  
West Ryde NSW 2114  
Tel: (02) 9325 4444 |
| KY   | Key Pharmaceuticals Pty Ltd  
12 Lyon Park Road  
MACQUARIE PARK NSW 2113  
Tel: (02) 8113 6200 |
| LB   | Life Bioscience Pty Ltd  
10 Atherton Road  
OAKLEIGH VIC 3166  
Tel: 1800 114 610 |
| LM   | Link Medical Products Pty Ltd  
Unit 1  
5 Apollo Street  
WARRIEWOOD NSW 2102  
Tel: +61 (0)2 8401 9777 |
| LN   | Aspen Pharmacare Australia Pty Limited  
34-36 Chandos Street  
ST LEONARDS NSW 2065  
Tel: (02) 8436 8000 |
| LO   | Leo Pharma Pty Ltd  
Level 3, Tower 1  
25 Montpelier Road  
Bowen Hills QLD 4006  
Tel: (07) 32501200 |
| LU   | Lundbeck Australia Pty Ltd  
Ground Floor  
1 Innovation Road  
NORTH SYDNEY NSW 2113  
Tel: (02) 88691000 |
| LY   | Eli Lilly Australia Pty Ltd  
112 Wharf Road  
West Ryde NSW 2114  
Tel: (02) 9325 4444 |
| MD   | Roche Products Pty Ltd  
4-10 Inman Road  
DEE WHY NSW 2099  
Tel: +61 (0)2 9454 9000  
Fax: +61 (0)2 9971 7401 |
| MF   | Mundipharma Pty Limited  
50 Bridge Street  
SYDNEY NSW 2000  
Tel: 02 9231 7200 |
| MH   | Molnlycke Health Care Pty Ltd  
Building 1, Ground Floor 14 Aquatic Drive  
Frenchs Forest NSW 2086  
Tel: +61 (0)2 9453 1144  
Fax: +61 (0)2 9453 1155 |
| MK   | Merck Sharp & Dohme (Australia) Pty Ltd  
Level 1, Building A  
26 Talavera Road  
MACQUARIE PARK NSW 2113  
Tel: +61 (0)2 8988 8000 |
| MM   | 3M Pharmaceuticals Australia Pty Ltd  
9-15 Chilvers Road  
Thornleigh NSW 2120  
Tel: (02) 9875 6333 |
| MQ   | Alphapharm Pty Ltd  
Level 1  
30 The Bond, 30-34 Hickson Rd  
MILLERS POINT NSW 2000  
Tel: 1800 028 365 |
| MS   | Abbott Australasia Pty Ltd  
Sir Joseph Banks Corporate Park  
32-34 Lord Street  
BOTANY NSW 2019  
Tel: 1800 801 478 |
| MT   | Mentholatum Australasia Pty Ltd  
12-16 Janine Street  
Scoresby VIC 3179  
Tel: (03) 9763 0322 |
| MW   | Biomed Aust Pty Limited  
C/o Robinson Legal  
Level 4, 250 Kent Street  
SYDNEY NSW 2000  
Tel: +61 (0)2 9815 5405 |
| NA   | National Diagnostic Products (Australia) Pty Limited  
7-9 Merriwa Street  
GORDON NSW 2072  
Tel: +61 (0)2 9418 4777  
Fax: +61 (0)2 9418 4747 |
| NC   | Novartis Consumer Health Australasia Pty Ltd  
327-333 Police Road  
MULGRAVE VIC 3170  
Tel: 1800 069 643 |
| NE   | Norgine Pty Limited  
Unit 3, 14 Rodborough Road  
FRENCHS FOREST NSW 2086  
Tel: 1800 636 000 |
| NF   | Novo Nordisk Pharmaceuticals Pty Limited  
Level 3, 21 Solent Circuit  
BAULKHAM HILLS NSW 2153  
Tel: (02) 8858 3600 |
| NI   | Novo Nordisk Pharmaceuticals Pty Limited  
Level 3, 21 Solent Circuit  
BAULKHAM HILLS NSW 2153  
Tel: (02) 8858 3600 |
| NJ   | Norac Pharma Australia Pty Ltd  
Suite 401  
7 Oaks Avenue  
DeeWhy NSW 2099  
Tel: +61 (0)2 9981 4470 |
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Tel: 1800 671 203 |
| NO   | Novo Nordisk Pharmaceuticals Pty Limited  
Level 3, 21 Solent Circuit  
Baulkham Hills NSW 2153  
Tel: (02) 8858 3600 |
| NQ   | Takeda Pharmaceuticals Australia Pty Ltd  
Ground Floor, 2-4 Lympark Road  
MACQUARIE PARK NSW 2113  
Tel: +61 (0)2 9859 6900  
Fax: +61 (0)2 9859 6950 |
| NT   | Nestle Australia Ltd  
20-24 Howleys Road  
Notting Hill VIC 3168  
Tel: 1800 025 361 |
| NU   | Nutricia Australia Pty Limited  
Level 4, Building D  
12-24 Talavera Road  
Macquarie Park NSW 2113  
Tel: +61 (0)2 8875 0300 |
| NV   | Novartis Pharmaceuticals Australia Pty Limited  
54 Waterloo Road  
North Ryde NSW 2113  
Tel: 1800 671 203 |
| NX   | Nipro Australia Pty Ltd  
Suite 3, 500 Pacific Hwy  
ST LEONARDS NSW 2065  
Tel: 1800 451 737 |
| OA   | Orphan Australia Pty Ltd  
First Floor  
34-36 Chandos Street  
ST LEONARDS NSW 2065  
Tel: (02) 8436 8300 |
| OB   | Oral B Laboratories Pty Ltd  
Level 3, 90 Mount Street  
North Sydney NSW 2060  
Tel: (02) 9957 6499 |
| OE   | Omegapharm Pty Ltd  
21 Queen Street  
ORMOND VIC 3204  
Tel: +61 (0)418 351 065 |
| OI   | Boian Surgical Pty Ltd  
486 King georges Road  
BEVERLY HILLS NSW 2209  
Tel: (02) 9580 7447 |
| OL   | Owen Laboratories Division of Galderma Australia Pty Ltd  
9 Rodborough Road  
Frenchs Forest NSW 2086  
Tel: 1800 800 765 |
| OM   | Colgate Oral Care  
345 George Street  
Sydney NSW 2000  
Tel: (02) 9229 5600 |
| ON   | Orion Laboratories Pty Ltd  
25-29 Delawney Street  
Balcatta WA 6021  
Tel: 1800 004 110 |
| OZ   | Medical Specialties Australia Unit Trust  
54 Gibbs Street  
Chatswood NSW 2067  
Tel: (02) 9417 7955 |
| PE   | Allergan Australia Pty Limited  
Level 4  
810 Pacific Highway  
Gordon NSW 2072  
Tel: 1800 252 224 |
| PF   | Pfizer Australia Pty Ltd  
38-42 Wharf Road  
WEST RYDE NSW 2114  
Tel: +61 (0)2 9850 3333 |
| PK   | Fresenius Kabi Australia Pty Limited  
964 Pacific Highway  
PYMBLE NSW 2073  
Tel: 1800 181 537 |
| PL   | The Trustee for Virgo Unit Trust (trading as Phebra)  
19 Orion Road  
Lane Cove West NSW 2066  
Tel: 1800 720 020 |
| PM   | Pharmaceutical Manufacturing Company Pty Limited  
5 Alma Road  
NORTH RYDE NSW 2113  
Tel: (02) 9978 3500 |
| PP   | Petrus Pharmaceuticals Pty Ltd  
PO Box 1808  
WEST PERTH WA 6872  
Tel: +61 (0)8 9368 5954 |
| PQ   | PMIP Pty Ltd  
Unit 1  
5 Apollo Street  
WARRIEWOOD NSW 2102  
Tel: +61 (0)2 8401 9777 |
| PX   | Point of Care Diagnostics Australia Pty Ltd  
Unit 14  
76 Reserve Road  
ARTARMON NSW 2064  
Tel: (02) 9437 1355 |
| PY   | Procter & Gamble Pharmaceuticals Australia Pty Ltd  
99 Phillip Street  
Parramatta NSW 2150  
Tel: (02) 9685 4500 |
| QA   | Aspen Pharma Pty Ltd  
34-36 Chandos Street  
ST LEONARDS NSW 2065  
Tel: (02) 8436 8300 |
| QB   | Bionime Australia Pty Limited  
75/359 Pitt Street  
SYDNEY NSW 2000  
Tel: (02) 9262 6900 |
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Suite 3  
309 Hampton Street  
Hampton VIC 3188  
Tel: 1800 367 758  
Fax: +61 (0)3 8677 7663 |
| QL   | Amcla Pty Limited  
Unit 4/490 Frankston Dandenong Road  
CARRUM DOWNS VIC 3201  
Tel: +61 (0)3 9782 4777 |
| RA   | Ranbaxy Australia Pty Limited  
Ground Floor  
9-13 Waterloo Road  
NORTH RYDE NSW 2113  
Tel: +61 (0)2 9887 2600 |
| RB   | Bio Revive Pty Ltd  
182-184 Stawell St  
Burnley VIC 3121  
Tel: +61 (0)3 8416 0399 |
| RC   | Reckitt Benckiser (Australia) Pty Limited  
44 Wharf Road  
West Ryde NSW 2114  
Tel: 1800226766 |
| RD   | Roche Diagnostics Australia Pty Limited  
31 Victoria Avenue  
CASTLE HILL NSW 2154  
Tel: 1800 251 816 |
| RI   | Dr Reddy's Laboratories (Australia) Pty Ltd  
Level 1  
181 Bay Street  
BRIGHTON VIC 3186  
Tel: +61 (0)3 9595 3812  
Fax: +61 (0)3 9595 3800 |
| RO   | Roche Products Pty Ltd  
4-10 Inman Road  
DEE WHY NSW 2099  
Tel: +61 (0)2 9454 9000  
Fax: +61 (0)2 9971 7401 |
| RX   | Servier Laboratories (Aust.) Pty Ltd  
8 Cato Street  
HAWTHORN VIC 3122  
Tel: (03) 8823 7333 |
| RZ   | Dr Reddy's Laboratories (Australia) Pty Ltd  
Level 1  
181 Bay Street  
BRIGHTON VIC 3186  
Tel: +61 (0)3 9595 3812  
Fax: +61 (0)3 9595 3800 |
| SA   | SciGen (Australia) Pty Limited  
Suite 1  
13B Narabang Way  
BELROSE NSW 2085  
Tel: 1800 966 303 |
| SB   | Nutricia Australia Pty Limited  
Level 4, Building D  
12-24 Talavera Road  
Macquarie Park NSW 2113  
Tel: +61 (0)2 8875 0300 |
| SE   | Servier Laboratories (Aust.) Pty Ltd  
8 Cato Street  
HAWTHORN VIC 3122  
Tel: (03) 8823 7333 |
| SG   | Merck Serono Australia Pty Ltd  
Unit 3-4, 25 Frenchs Forest Road East  
Frenchs Forest NSW 2086  
Tel: +61 (0)2 8977 4100 |
| SI   | Sigma Company Limited  
3 Myer Place  
ROWVILLE VIC 3178  
Tel: 03 9215 9215 |
| SJ   | Sharpe Laboratories Pty Ltd  
12 Hope Street  
Melrose Park NSW 2114  
Tel: +61 (0)2 9858 5622 |
| SN   | Smith & Nephew Pty Limited  
315 Ferntree Gully Road  
Mount Waverley VIC 3149  
Tel: 13 13 60 |
| SS   | SSL Australia Pty Ltd  
225 Beach Road  
Mordialloc VIC 3195  
Tel: 1800 999 155 |
| SW   | sanofi-aventis Australia Pty Ltd  
Building D, Talavera Corporate Centre  
12-24 Talavera Road  
MACQUARIE PARK NSW 2113  
Tel: +61 (0)2 8666 2000 |
| SY   | Bayer Australia Ltd  
875 Pacific Highway  
PYMBLE NSW 2041  
Tel: 1800 673 270 |
| SZ   | Sandoz Pty Ltd  
Suite 201, Level 2  
19 Harris Street  
Pyrmont NSW 2009  
Tel: 1800 726 369 |
| TK   | Takeda Pharmaceuticals Australia Pty Ltd  
Ground Floor, 2-4 Lygonpark Road  
MACQUARIE PARK NSW 2113  
Tel: +61 (0)2 9859 6900  
Fax: +61 (0)2 9859 6950 |
| TL   | Tolmar Australia Pty Ltd  
Building 2, Level 2, Suite 4  
20 Bridge Street  
Pymble NSW 2073  
Tel: +61 (0)2 9440 6700 |
| TM   | Technipro Marketing Pty Ltd  
PO Box 38  
OATLANDS NSW 2117  
Tel: +61 (0)2 9897 5899 |
| TS   | Specialised Therapeutics Australia Pty Ltd  
PO Box 250  
EAST KEW VIC 3102  
Tel: 1300 798 820 |
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Section 1 — Explanatory Notes

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

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

The aim of the PBS, which has been in operation since 1948, is to provide reliable and affordable access to a wide range of necessary medicines.

The Schedule of Pharmaceutical Benefits referred to throughout as the ‘Schedule’ – lists all the medicinal products available under the PBS, and explains the uses for which they can be subsidised.

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

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

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

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

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

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

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

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

Section 2
This section lists ready-prepared items, and includes the form, manner of administration, brand and brand equivalents which may be prescribed, and the maximum quantity and number of repeats for each item.

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

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

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

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

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

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

Section 3
This section lists container prices, fees related to dispensing, standard packs and prices for ready-prepared preparations.
Section 4

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

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

Repatriation Schedule of Pharmaceutical Benefits

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

2. Prescribing Medicines – Information for PBS Prescribers

PBS prescribers

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

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

PBS Prescription forms

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

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

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

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

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

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

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

The inclusion of the prescriber number on a PBS prescription enables the pharmacist to be sure the prescription is from a legitimate prescriber and satisfies State/Territory legislation. A PBS prescription written by a dentist, an optometrist, a midwife or a nurse practitioner must include the person’s approval number as a PBS prescriber.

PBS prescriptions should be provided to the patient in duplicate, as both parts make up a valid PBS prescription. The patient should be reminded to present both the original and the duplicate copy to the pharmacist.

PBS stationery order forms

Prescribers are asked not to over order. Getting the right amount of forms helps to reduce the cost to taxpayers and helps to reduce paper wastage. Also, the pads may deteriorate if stored over time.

Prescribers can gain access to order forms for standard and authority prescription forms as well as computer prescription forms by
downloading the required order form from the Department of Human Services website at www.humanservices.gov.au.

The completed order form should be posted to:

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

**Preparation general PBS prescriptions**

**Do's and Don't's**

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

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

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

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

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

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

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

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

The following admixtures are not pharmaceutical benefits:

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

**Writing the PBS prescription**

The following rules apply for writing PBS prescriptions:

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

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

**Unrestricted benefits** - have no restrictions on their therapeutic uses;

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

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

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

Authority PBS prescriptions

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

All PBS prescribers (with the exception of dentists) can write authority PBS prescriptions.

Authority PBS prescriptions cannot have retrospective approval.

**Authority required PBS Prescriptions**

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

- posting an Authority Prescription Form to the Department of Human Services - after approval, the Department of Human Services will forward both copies of the prescription to the patient or the prescriber (if it is to be sent direct to the patient, the prescriber should mark the box next to the patient's details);

- calling the Department of Human Services Telephone Authority Applications Freecall service (1800 888 333); or


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

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

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

- the patient/pharmacist copy, which records prescriber, patient, and pharmaceutical benefit item details. Where required a repeat authorisation, which is used for repeat supply, is attached to the pharmacist/patient copy until the last supply is made. The patient/pharmacist copy is then retained by the pharmacist;

- the Department of Human Services/DVA copy which records prescriber, patient, and pharmaceutical benefit item details. After the first dispensing, the Department of Human Services/DVA copy is forwarded to the Department of Human Services for processing and payment;

- the prescriber’s copy (for computer generated scripts, this is the tear off portion at the base of the script) or Prescriber/the Department of Human Services/DVA copy (for handwritten scripts this is the long white copy), is kept by the Department of Human Services or the DVA for record purposes when approval is sought in writing. When approval is by telephone or by the authorities website, the prescriber must keep this copy for 12 months. This copy must record the daily dose, details of the disease, clinical justification for using the item, the patient’s age (if the patient is a child) and whether the patient has previously received an authority for this pharmaceutical benefit.

**Authority required (STREAMLINED) PBS Prescriptions**

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

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

There are no Authority Required (STREAMLINED) items in the Repatriation Schedule of Pharmaceutical Benefits.

Authority required (STREAMLINED) PBS prescriptions must be written on an Authority PBS/RPBS Prescription Form, this includes:

- the pharmacist/patient copy, which records prescriber, patient, and pharmaceutical benefit item details. The prescription is given directly to the patient to be dispensed at their pharmacy;

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

**Writing authority PBS prescriptions**

The following rules apply:

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

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

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

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

**Maximum quantities and repeats**

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

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

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

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

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

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

**Regulation 24**

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

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

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

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

**Urgent cases**

In urgent cases and where State/Territory law allows, a prescriber may telephone a pharmacist and ask that a PBS prescription be supplied. He/she must then forward the written PBS prescription and duplicate to the pharmacist within **seven days of the date of supply**.
This also applies to 'Authority required' authority PBS prescriptions provided prior approval has been given by the Department of Human Services or DVA. The follow-up written PBS prescription must include the approval number provided over the phone by the Department of Human Services or DVA.

**Drugs of addiction**

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

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

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

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

**Prescriber bag supplies**

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

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

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

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

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

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

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

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

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

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

**How to prescribe these items?**

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

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

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

**Aboriginal and Torres Strait Islander identification**

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

Improving the level of identification of Aboriginal and Torres Strait Islander people will also assist in developing initiatives to meet particular needs.

For the purposes of these PBS items a person is Aboriginal and/or Torres Strait Islander if the person identifies himself or herself as being an Aboriginal and/or Torres Strait Islander. Clients should be asked to self-identify either verbally or by completing a form.

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

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

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

Aboriginal and Torres Strait Islander health

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

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

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

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

Communication and cultural issues

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

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


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

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

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

You should:

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

3. Supplying Medicines — What Pharmacists Need to Know

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

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

Unapproved pharmacists cannot supply pharmaceutical benefits.

Approval conditions for pharmacists
A pharmacist approved to supply medicines under the PBS:
• can only supply benefits from the pharmacy that he/she is operating;
• will not supply to anyone any pharmaceutical benefit that attracts a Commonwealth contribution for free, or for a price that is less than the relevant patient contribution;
• will clearly advertise that any offer for free or cut-price medicines does not include pharmaceutical benefits which have a Commonwealth contribution;
• will not pay rebates or refunds of patient contributions;
• will publicly display a notice setting out the pharmacy’s normal trading hours;
• is obliged to supply pharmaceutical benefits at the pharmacy at any hour if a PBS prescription is marked ‘urgent’ and initialled by the prescriber;
• will keep adequate stocks for the supply of pharmaceutical benefits;
• may be called on by the Department of Human Services to provide details of stocks of pharmaceutical benefits or preparations for pharmaceutical benefits; and
• must keep the duplicates of all old format PBS prescriptions, and the patient/pharmacist copies of all new format PBS prescriptions, with a Commonwealth contribution for at least one year from the date of supply. This includes PBS prescriptions ordering repeats when it is the final supply, and order forms for prescriber bag supplies. Please note that some State/Territory laws require these copies to be kept for longer periods.

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

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

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

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

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

Supplying pharmaceutical benefits
Do’s and Don’ts
Except in urgent cases (see details under ‘2. Prescribing Medicines ... Urgent cases’), pharmacists are authorised to supply pharmaceutical benefits only after they receive:
• the pharmacist/patient and the Department of Human Services or DVA copies of a valid PBS prescription which is not more than 12 months old; or
• the pharmacist/patient and the Department of Human Services or DVA copies of an approved authority PBS prescription or an authority to prescribe which is not more than 12 months old; or
• a repeat authorisation attached to a patient/pharmacist PBS prescription not more than 12 months after the date of the original PBS prescription.

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

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

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

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

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

Exceptions to this are:

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

A pharmacist can supply an alternative pharmaceutical benefit without reference to the prescriber, provided that:

• the PBS prescription does not indicate that only the pharmaceutical benefit prescribed is to be supplied (i.e., substitution is not permitted); and
• the Schedule states that the prescribed benefit and the substitute benefits are equivalent; and
• supply of the substitute benefit does not contravene relevant State/Territory law; and
• the substitute benefit is a listed brand in the Schedule.

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

**What to do if the Schedule changes**

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

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

**Suspected forgery**

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

**Regulation 24**

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

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

**Repeat authorisations**

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

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

**Preparing Repeat Authorisation Forms**

A Repeat Authorisation Form must show:

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

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

**Repeat authorisations for deferred supply**

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

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

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

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

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

**Authority PBS prescriptions**

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

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

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

**Urgent cases**

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

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

**Receipts**

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

If a pharmaceutical benefit has to be sent through the post, by rail, or by other means, and a receipt is not practical, the pharmacist must certify on the PBS prescription or repeat authorisation that the benefit has been supplied, and write the date of supply and details of how it was sent. For example, if a pharmaceutical benefit is mailed to a patient on 1 April 2008, the pharmacist should write: “Certified supplied – mailed to patient 1 April 2008 (name of pharmacist) (signature of pharmacist) (date of certification)”. If an item is supplied in an urgent case, or to a person who cannot read or write, the pharmacist should sign and date a statement on the PBS prescription or repeat authorisation, stating the item has been supplied and the date on which it was supplied, and explaining why there is no receipt. For example, if a pharmaceutical benefit is supplied to a patient with a broken arm on 1 May 2008, the pharmacist should write: “Certified supplied 1 May 2008 – patient has a broken arm and is unable to sign (name of pharmacist) (signature of pharmacist) (date of certification)”.

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

**Prescriber bag supplies**

Pharmacists may supply certain pharmaceutical benefit items free of charge to a PBS prescriber if they receive a prescriber bag order form in duplicate, signed by the prescriber. Only items listed under prescriber bag provisions for the relevant prescriber type can be supplied to the prescriber.
Pharmacists must be satisfied the form was completed by a PBS prescribers and includes the prescriber’s name and address. If a pharmacist does not know the prescriber, he/she should confirm the prescriber’s registration or PBS prescriber number and endorse this on the back of the form.

For more information see '2. Prescribing Medicines ... Prescriber bag supplies'.

4. Patient Charges

Type of patient

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

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

Concessional patients are recognised by public hospitals in all States and Territories apart from South Australia (where DVA beneficiaries are treated as general patients) and New South Wales (where holders of a white DVA card are treated as general patients).

Under the Reciprocal Health Care Agreements, visitors from participating countries (see the introduction of this section for the list of countries) are treated as general patients and do not have concessional entitlements. To receive pharmaceutical benefits these visitors may need to present a temporary Medicare card or their passport. Pharmacists should contact the Department of Human Services if they have enquiries about these arrangements.

Establishing entitlement

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

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

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

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

What to charge

Patient contribution

Under the PBS, the maximum cost for a pharmaceutical benefit item at a pharmacy is $36.90 for general patients and $6.00 for concessional patients, plus any applicable special patient contribution, brand premium or therapeutic group premium. General patients who have reached the safety net threshold (see details under ‘5. The Safety Net Scheme’) may receive pharmaceutical benefits at the concessional rate, plus any applicable special patient contribution, brand premium or therapeutic group premium.

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

The contribution rate for general patients as outpatients at public hospitals in most of Australia is $29.50. The exceptions are in Queensland and in hospitals participating in the pharmaceutical reforms where they pay the safety net value of an item listed in the Schedule (see details under ‘5. The Safety Net Scheme’), or up to the general co-payment amount for items not listed in the Schedule. The public hospital pharmaceutical reforms enable participating public hospitals to prescribe and supply pharmaceutical medication from the PBS to outpatients and patients upon discharge. A range of chemotherapy drugs is also available for day-admitted and non-admitted chemotherapy patients.

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

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

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

The patient contribution rates are adjusted on 1 January each year in line with inflation.
**Patient contributions for early supply of some PBS medicines**

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

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

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

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

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

**Special patient contributions, brand premiums and therapeutic group premiums**

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

Under the brand premium arrangements, reimbursement to pharmacists is based on the lowest-priced brand. Any extra charge for a higher priced brand is paid by the patient, together with their usual patient contribution.

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

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

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

**Increased quantities**

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

**Regulation 24**

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

**After hours**

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

**Delivery**

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

**5. The Safety Net Scheme**

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

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

The scheme requires pharmacists, on request by patients, to record the supply of PBS and RPBS items on prescription record forms. When a patient reaches the Safety Net threshold within a calendar year, they qualify to receive PBS or RPBS items at a cheaper price or free of charge for the rest of that year. Any applicable special patient contributions, brand premiums or therapeutic group premiums must still be met by the patient.
The safety net threshold is reached by accumulating eligible patient contributions for PBS prescriptions supplied through community pharmacies and private hospitals and for out-patient medication supplied by public hospitals.

Pharmaceutical benefits (including authority items) can only be counted towards the safety net threshold when prescribed and supplied according to PBS conditions. A medicine supplied by a pharmacist not approved to supply pharmaceutical benefits cannot count towards the safety net.

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

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

**Safety net thresholds**

There are two safety net thresholds. The general patient safety net threshold is currently $1,421.20. When a person and/or their family's total applicable co-payments reach this amount, they may apply for a safety net concession card and pay the concessional co-payment amount of $6.00 plus any applicable premium for pharmaceutical benefits for the rest of that calendar year.

The concessional safety net threshold is $360.00 (this also applies to gold, white or orange card holders under the RPBS). When a patient and/or their family's total applicable co-payments reach this amount, they may apply for a safety net entitlement card and may receive pharmaceutical benefits free of charge (except for any applicable premium) for the rest of that calendar year.

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

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

**Safety net cross-over arrangements**

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

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

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

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

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

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

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

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

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

**Recording PBS prescriptions**

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

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

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

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

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

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

Some computer software suppliers provide a special label to record this information on the prescription record forms. Some suppliers also provide a computer printout as a prescription record form.

The patient is responsible for maintenance and storage of their prescription record form. However, it may be kept in the pharmacy. A person (or family) may have more than one prescription record form.

**Hospital prescription record forms**

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

**Multi-item prescription forms**

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

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

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

**Qualifying PBS prescriptions**

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

**Lost prescription record forms**

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

**Retrospective entitlement and patient refunds**

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

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

If the patient cannot satisfy a pharmacist that they have a current entitlement and is charged the general patient price, the pharmacist should issue the patient with a receipt and a claim form (provided by the Department of Human Services). The patient can then obtain a refund via Medicare Service Centres or PBS processing centres. RPBS prescription refunds are paid at DVA State offices.
The Department of Human Services can only pay refunds for PBS items supplied through approved pharmacies. Refunds for hospital supplied items should be referred to the relevant hospital or health department. Refunds cannot be made where the patient was charged the general or concessional amount instead of the safety net concessional or safety net entitlement amount as a result of the safety net 20 day rule. Receipts for prescriptions where the safety net 20 day rule has applied must include ‘SN20DR’ to indicate the reason for the amount charged.

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

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

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

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

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

When appropriate the pharmacist should check that the patient’s Medicare card number is on the prescription record form.

**Issuing a Safety Net Entitlement/Concession Card**

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

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

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

**Issuing supplementary cards**

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

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

**Notification to the Department of Human Services and claim for payment**

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

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

Payment will not be made for void cards.

**Lost Safety Net Entitlement/Concession Cards**

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

**Pharmacy record of issued cards**

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

**General Patients**

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

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

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

**Concessional Patients**

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

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

**Entitlement checking procedures**

**General Patients**

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

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

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

**Concessional Patients**

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

**Step by step**

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

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


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

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

**PBS Prescription identification**

Pharmacists must include certain information on each PBS prescription sent in for claim, as specified below. It is important that this information is entered correctly and in the right place on the PBS prescription. This information will be included in a sticker produced by pharmacy software.
The sticker should be placed on the extreme left front of a PBS prescription, opposite each item being claimed. It must not obscure any details written by the prescriber. Most prescribers use PBS prescriptions, which have space for the sticker. If a sticker is not used, a PBS prescription identification stamp can be used or the information can be written in the same place, and in the same order.

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

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

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

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

Serial numbers

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

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

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

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

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

Repeat authorisations for authority PBS prescriptions

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

Repeat authorisations for deferred supply

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

Dropper containers

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

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

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

PBS prescriptions paid on an average price basis

If the PBS prescription is to be claimed as an exceptional PBS prescription, the pharmacist should write details of the formula supplied on the PBS prescription or repeat authorisation form; price the PBS prescription in accordance with the pricing principles (as detailed in ‘9. Pricing PBS Prescriptions’); and enter the calculated price on the sticker.
An exceptional PBS prescription is for an extemporaneously-prepared pharmaceutical benefit that is not included in the Standard Formulae List and for which the price of the ingredients (based on basic pricing rules) is twice or more than the recovery price of the ingredients calculated on an average price basis. Further information on pricing PBS prescriptions can be accessed from the booklet titled Explanation of Current Pricing on the Department of Human Services' website at www.medicareaustralia.gov.au (PBS publications for Health Care Providers).

**Pricing non-pre-priced extemporaneous preparations**

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

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

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

**Payment to Pharmacists for Dispensing Premium-free Substitutable Medicines**

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

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

www.medicareaustralia.gov.au/provider/pbs/pharmacists/reforms.jsp#dispensing

8. How Pharmacists Claim Reimbursement: Documents to be Submitted

A claim for pharmaceutical benefits consists of:

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

PBS prescriptions in each bundle should be in serial number order, with serial number 1 at the top of the bundle.

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

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

**Completing the claim form**

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

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

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

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

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

**Lodging claims**

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

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

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

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

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

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

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

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

9. Pricing PBS Prescriptions

Pricing principles

The same pricing principles apply to all PBS prescriptions.

For ready-prepared pharmaceutical benefits, payment is made on the basis of the lowest-priced brand.

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

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

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

Pricing dates

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

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

Pricing ready-prepared items

For maximum quantities

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

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

For lesser quantities

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

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

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

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

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

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

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

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

Wastage Factor Table

<table>
<thead>
<tr>
<th>Column A</th>
<th>Column B</th>
</tr>
</thead>
<tbody>
<tr>
<td>5, 10, 15, 20, 25, 30, 35, 40, 45, 50, 55, 60, 65, 70, 75, 80, 85, 90, 95, 100</td>
<td></td>
</tr>
<tr>
<td>10, 18, 26, 32, 38, 44, 50, 54, 58, 62, 66, 70, 74, 78, 82, 86, 90, 94, 98, 100</td>
<td></td>
</tr>
</tbody>
</table>

The appropriate wastage table percentage is as follows:

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

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

**Pricing extemporaneously-prepared items**

**General**

The price payable for supplying the maximum quantity of standard formula preparations is shown in the Standard Formulae List. The following principles apply in determining prices of all pre-priced extemporaneous formulae on the list. They also apply when a pharmacist elects to price extemporaneous PBS prescriptions outside the list, including exceptional PBS prescriptions.

The amount payable is the sum of:

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

**Pricing of ingredients**

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

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

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

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

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

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

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

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

Where liquids are purchased by weight, the recovery price includes the ‘Specific Gravity Factor’.
Special pricing provisions apply to drugs marked '(a)' or '(b)' in the Drug Tariff.

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

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

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

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

**Containers**

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

A double size container is allowed for bulk powders.

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

If a pharmacist elects to price extemporaneous PBS prescriptions outside the Standard Formulae List, there can be no variation for three months. This applies to all extemporaneously-prepared formulae not on the list, and includes both PBS and RPBS prescriptions.

If a pharmacist does not elect to price out these PBS prescriptions, he/she will be paid at an average reimbursement rate.

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

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

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

Any variant to a formula included in the list (adding or deleting an ingredient or varying the dose) takes the formula dispensed outside the list.

When an ingredient is added to a standard formula and the recovery price for the standard formula plus additive under the average price system is less than for the standard formula alone, the pharmacist may have the PBS prescription priced as a basic standard formula item.

10. Miscellaneous

**References**

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

**Standards**

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

**Legislation**

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

**Nurse practitioner PBS prescribing**

**MEDICINES WHICH MAY BE PRESCRIBED BY AUTHORISED NURSE PRACTITIONERS**

From 1 September 2010, nurse practitioners endorsed to prescribe under state or territory legislation can apply for approval as PBS prescribers (authorised nurse practitioners). Information for nurse practitioners to become authorised PBS prescribers is available from the Department of Human Services.
The medicines listed for prescribing by authorised nurse practitioners from 1 November 2010 are identified by ‘NP’ in the PBS Schedule. Nurse practitioners must not write PBS prescriptions for other medicines.

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

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

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

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

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

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

Nurse practitioner PBS prescriptions are identifiable by colour, and include the indicator ‘NP’ on personalised forms and a tick box on non-personalised (blank) forms.

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

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

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

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

**Midwife PBS prescribing**

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

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

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

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

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

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

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

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

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

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

**Optometrist PBS prescribing**

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

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

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

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

Some products are included in more than one section of the Schedule, and for more than one prescriber type. For a prescription to be eligible for subsidy, prescribers must ensure that they prescribe under the PBS only those medicines, and in accordance with the restrictions, listed for their practitioner type.

Optometrist PBS prescriptions are identifiable by colour, and include the words ‘PBS/RPBS optometrist’. Prescriptions must include the optometrist’s PBS prescriber number. The same optometrist prescription form is used to prescribe unrestricted, restricted or authority items. Only one item is allowed per form. Optometrist PBS prescriptions may include repeats.

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

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

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

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

**GUIDELINES FOR SHARED CARE OF GLAUCOMA PATIENTS**

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

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

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

Initial Referral to Ophthalmologist

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

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

The patient’s consent is to be obtained by the ophthalmologist and optometrist for all aspects of the management plan, including the sharing of care between the two practitioners, and the communication of clinical information to the patient’s nominated general practitioner.
Patients being considered for anti-glaucoma therapy with a beta blocking agent should be assessed for any potential cardiovascular or respiratory risk by a medical practitioner (often the patient’s general practitioner), prior to initiating therapy. This assessment should be repeated if a change in dose of the beta blocker is proposed.

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

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

Patient Management Plan

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

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

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

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

SYMBOLS USED IN THE SCHEDULE

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

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

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

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

RESTRICTED BENEFITS

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

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

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

BRAND EQUIVALENCE

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

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

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

BRAND PREMIUM POLICY

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

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

Basically the policy operates by:

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

If a prescription is written generically or for the lowest priced brand, and the lowest priced brand is supplied, there is no brand premium payable.
'B' located immediately before an amount in the premium column indicates a brand premium which applies to that particular brand of the item.

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

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

**THERAPEUTIC GROUP PREMIUM POLICY**

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

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

Basically the policy operates by:

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

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

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

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

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

It should be noted that the brand premium or therapeutic group premium is not a Government charge or revenue. The premium arises from the manufacturer’s price and the majority goes to the manufacturer with wholesalers and pharmacists receiving a small percentage.
Prescriber Bag
<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Maner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>Dispensed Price for Max. Qty $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>3451P</td>
<td>ADRENALINE adrenaline 1 in 1000 (1 mg/mL) injection, 5 x 1 mL ampoules</td>
<td>1</td>
<td>20.68</td>
<td>Link Medical Products Pty Ltd LM</td>
</tr>
<tr>
<td>3453R</td>
<td>ATROPINE ATROPINE Injection 600 micrograms in 1 mL, 10</td>
<td>1</td>
<td>20.88</td>
<td>Pfizer Australia Pty Ltd PF</td>
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<tr>
<td>10016E</td>
<td>BENZTROPINE benzphetamine mesylate 2 mg/2 mL injection, 10 x 2 mL vials</td>
<td>1</td>
<td>287.65</td>
<td>Benztropine Omega FK</td>
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<td>or</td>
<td>BENZTROPINE benzphetamine mesylate 2 mg/2 mL injection, 5 x 2 mL ampoules</td>
<td>1</td>
<td>103.93</td>
<td>Cogentin FK</td>
</tr>
<tr>
<td>3457Y</td>
<td>BENZTROPINE benzphetamine mesylate 2 mg/2 mL injection, 5 x 2 mL ampoules</td>
<td>1</td>
<td>103.93</td>
<td>Cogentin FK</td>
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<tr>
<td>3466K</td>
<td>DIPHTHERIA TOXOID + TETANUS TOXOID diphtheria toxoid 2 international units/0.5 mL + tetanus toxoid 2 international units/0.5 mL injection, 5 x 0.5 mL syringes</td>
<td>4</td>
<td>*275.36</td>
<td>ADT Booster CS</td>
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<td>or</td>
<td>DIPHTHERIA TOXOID + TETANUS TOXOID diphtheria toxoid 2 international units/0.5 mL + tetanus toxoid 2 international units/0.5 mL injection, 5 x 0.5 mL syringes</td>
<td>1</td>
<td>16.83</td>
<td>Solu-Cortef PF</td>
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<td>3458B</td>
<td>DIAZEPAM diazepam 10 mg/2 mL injection, 5 x 2 mL ampoules</td>
<td>1</td>
<td>13.68</td>
<td>Hospira Pty Limited HH</td>
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<tr>
<td>3463G</td>
<td>DICYCLOMEN HYDROCHLORIDE dicyclofenac hydrochloride 10 mg injection [1 x 100 mg vial] &amp; inert substance diluent [1 x 2 mL vial], 1 pack</td>
<td>2</td>
<td>*18.04</td>
<td>Solu-Cortef PF</td>
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<tr>
<td>or</td>
<td>DICYCLOMEN HYDROCHLORIDE dicyclofenac hydrochloride 10 mg injection [1 x 100 mg vial] &amp; inert substance diluent [1 x 2 mL vial], 1 pack</td>
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<td>16.83</td>
<td>Solu-Cortef PF</td>
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<td>or</td>
<td>GLYCERYL TRINITRATE glyceryl trinitrate 400 microgram/actuation spray, 200 actuations</td>
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<td>20.47</td>
<td>Nitrolingual Pumpspray SW</td>
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<td>FRUSEMIDE frusemide 20 mg/2 mL injection, 5 x 2 mL ampoules</td>
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<td>9.65</td>
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<td>or</td>
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<td>APO-Salbutamol TX</td>
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<tr>
<td>NP</td>
<td>salbutamol 2.5 mg/2.5 mL inhalation: solution, 30 x 2.5 mL ampoules</td>
<td>‡1</td>
<td>11.96</td>
<td>Ventolin Nebules GK</td>
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<tr>
<td>NP</td>
<td>salbutamol 5 mg/2.5 mL inhalation: solution, 30 x 2.5 mL ampoules</td>
<td>‡1</td>
<td>11.60</td>
<td>Asmol 5 uni-dose AF</td>
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<td>Salbutamol-GA GN</td>
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<td>3497C</td>
<td><strong>SALBUTAMOL</strong> salbutamol 5 mg/2.5 mL inhalation: solution, 30 x 2.5 mL ampoules</td>
<td>1</td>
<td>12.18</td>
<td>a Ventolin Nebules GK</td>
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<tr>
<td>3491R</td>
<td><strong>TERBUTALINE</strong> terbutaline sulfate 500 microgram/mL injection, 5 x 1 mL ampoules</td>
<td>1</td>
<td>30.93</td>
<td>Bricanyl AP</td>
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<td>3484J</td>
<td><strong>TRAMADOL</strong> tramadol hydrochloride 100 mg/2 mL injection, 5 x 2 mL ampoules</td>
<td>1</td>
<td>12.51</td>
<td>a Tramal 100 CS</td>
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<td></td>
<td>a Tramadol Sandoz SZ</td>
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<td>a Tramadol ACT GN</td>
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General Pharmaceutical Benefits
**ALIMENTARY TRACT AND METABOLISM**

### STOMATOLOGICAL PREPARATIONS

**Antiinfectives and antiseptics for local oral treatment**

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<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
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<th>Maximum Recordable Value for Safety Net</th>
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<td>amphotericin B 10 mg lozenge, 20</td>
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<td>1</td>
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<td>12.37</td>
<td>13.52</td>
<td>Fungilin QA</td>
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<td>3306B</td>
<td>amphotericin B 10 mg lozenge, 20</td>
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<td>..</td>
<td>12.37</td>
<td>13.52</td>
<td>Fungilin QA</td>
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<td>3033P</td>
<td>nystatin 100 000 international units/mL oral liquid, 24 mL</td>
<td>†1</td>
<td>1</td>
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<td>11.48</td>
<td>12.63</td>
<td>Mycostatin FM</td>
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<td>3343Y</td>
<td>nystatin 100 000 international units/mL oral liquid, 24 mL</td>
<td>†1</td>
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<td>..</td>
<td>11.48</td>
<td>12.63</td>
<td>Nilstat QA</td>
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**Other agents for local oral treatment**

**BENZYDAMINE**

*Restricted benefit*

Radiation induced mucositis

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<tr>
<td>1121B</td>
<td>benzydamine hydrochloride 0.15% mouthwash, 500 mL</td>
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<td>23.75</td>
<td>Difflam IA</td>
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<td>5032W</td>
<td>benzydamine hydrochloride 0.15% mouthwash, 500 mL</td>
<td>†1</td>
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<td>22.60</td>
<td>23.75</td>
<td>Difflam IA</td>
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### DRUGS FOR ACID RELATED DISORDERS

**ANTACIDS**

*Combinations and complexes of aluminium, calcium and magnesium compounds*

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<th>No. of Rpts</th>
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<tr>
<td>2159P</td>
<td>aluminium hydroxide 250 mg/5 mL + magnesium hydroxide 120 mg/5 mL + magnesium trisilicate 120 mg/5 mL oral liquid, 500 mL</td>
<td>2</td>
<td>5</td>
<td>...</td>
<td>*18.04</td>
<td>19.19</td>
<td>Gastrogel FM</td>
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<tr>
<td>2157M</td>
<td>aluminium hydroxide with MAGNESIUM HYDROXIDE Oral suspension 200 mg-200 mg per 5 mL, 500 mL, 1</td>
<td>2</td>
<td>5</td>
<td>...</td>
<td>*18.04</td>
<td>19.19</td>
<td>Mylanta P JT</td>
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</tbody>
</table>

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

**H2-receptor antagonists**

**CIMETIDINE**

*Note*

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

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<th>Maximum Recordable Value for Safety Net</th>
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<td>17.11</td>
<td>18.26</td>
<td>Magicul 400 AF</td>
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**FAMOTIDINE**

*Note*

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

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<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
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<td>2487X</td>
<td>famotidine 20 mg tablet, 60</td>
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<td>12.73</td>
<td>13.88</td>
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*Chem mart Famotidine CH*  
*Famotidine AN EA*  
*Famotidine Sandoz SZ*  
*GenRx Famotidine GX*  
*Pamacid 20 AF*
ALIMENTARY TRACT AND METABOLISM

Proton pump inhibitors

ESOMEPRAZOLE

Restricted benefit
Maintenance of healed gastro-oesophageal reflux disease

Restricted benefit
Scleroderma oesophagus

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

Note
**ALIMENTARY TRACT AND METABOLISM**

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<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
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<td>25.37</td>
<td>26.52</td>
<td>a Esomeprazole RBX RA</td>
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</tbody>
</table>

**ESOMEPRAZOLE**

**Restricted benefit**

Initial treatment of gastric ulcer

**Note**

Helicobacter pylori eradication therapy should be considered.

**Note**

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

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
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<td>25.37</td>
<td>26.52</td>
<td>a Esomeprazole RBX RA</td>
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</tbody>
</table>

**ESOMEPRAZOLE**

**Authority required**

Pathological hypersecretory conditions including Zollinger-Ellison syndrome and idiopathic hypersecretion

**Authority required**

Scleroderma oesophagus

**Note**

Continuing Therapy Only:

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

<table>
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<th>Code</th>
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<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
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<td>38.32</td>
<td>36.90</td>
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</table>

**ESOMEPRAZOLE**

**Restricted benefit**

Healing of gastro-oesophageal reflux disease

**Note**

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

<table>
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<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
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<td>8601QNP</td>
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<td>38.32</td>
<td>36.90</td>
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**LANSOPRAZOLE**

**Restricted benefit**

Gastro-oesophageal reflux disease

**Restricted benefit**

Scleroderma oesophagus

<table>
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<tr>
<th>Code</th>
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<th>No. of Rpts</th>
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<td>8198LNP</td>
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<td>9331DNP</td>
<td>lansoprazole 15 mg tablet: orally disintegrating, 28 tablets</td>
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<td>14.74</td>
<td>15.89</td>
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</table>

**LANSOPRAZOLE**

**Restricted benefit**

Initial treatment of peptic ulcer

**Note**

Helicobacter pylori eradication therapy should be considered.

**Note**

No applications for increased repeats will be authorised.

**Note**

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

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<td>22.24</td>
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**Note**

No applications for increased maximum quantities will be authorised.
<table>
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### OMEPRAZOLE

**Restricted benefit**
Gastro-oesophageal reflux disease

**Restricted benefit**
Scleroderma oesophagus

**Restricted benefit**
Zollinger-Ellison syndrome

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

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### PANTOPRAZOLE

**Restricted benefit**
Gastro-oesophageal reflux disease

**Restricted benefit**
Scleroderma oesophagus

**Restricted benefit**
Zollinger-Ellison syndrome

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**PANTOPRAZOLE**

*Restricted benefit*

Initial treatment of peptic ulcer

**Note**

Helicobacter pylori eradication therapy should be considered.

**Note**

No applications for increased repeats will be authorised.

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**RABEPRAZOLE**

*Restricted benefit*

Gastro-oesophageal reflux disease

*Restricted benefit*
### Scleroderma oesophagus

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**RABEPRAZOLE**

**Restricted benefit**

Initial treatment of peptic ulcer

**Note**

Helicobacter pylori eradication therapy should be considered.

**Note**

No applications for increased repeats will be authorised.

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**Combinations for eradication of Helicobacter pylori**

**ESOMEPRAZOLE (&) CLARITHROMYCIN (&) AMOXYCILLIN**

**Restricted benefit**

Eradication of Helicobacter pylori associated with peptic ulcer disease
### Other drugs for peptic ulcer and gastro-oesophageal reflux disease (GORD)

**ALGINATE SODIUM + CALCIUM CARBONATE + BICARBONATE**

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**SUCRALFATE**

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### BELLADONNA AND DERIVATIVES, PLAIN

**Belladonna alkaloids, tertiary amines**

**ATROPINE**

*Note*

Shared Care Model:

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

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**PROPULSIVES**

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### ANTIEMETICS AND ANTINAUSEANTS

**ANTIEMETICS AND ANTINAUSEANTS**

**Serotonin (5HT3) antagonists**

**GRANISETRON**

Restricted benefit

Nausea and vomiting

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

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

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**ONDANSETRON**

**Authority required (STREAMLINED)**

3611
Management of nausea and vomiting associated with radiotherapy being used to treat malignancy

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

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**ONDANSETRON**

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

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

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

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**ONDANSETRON**

**Authority required (STREAMLINED)**

3611
Management of nausea and vomiting associated with radiotherapy being used to treat malignancy

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## ALIMENTARY TRACT AND METABOLISM

### Ondansetron

**Restricted benefit**

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

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

### Palonosetron

**Restricted benefit**

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

**Note**

No applications for increased maximum quantities will be authorised. Palonosetron is not PBS-subsidised for administration with oral 5-HT3 antagonists.

### Tropisetron

**Restricted benefit**

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

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

### Other Antiemetics

**Aprepitant**

**Authority required (STREAMLINED)**

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## Nausea and vomiting

### Clinical criteria:
The condition must be associated with cytotoxic chemotherapy being used to treat malignancy,

AND

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

AND

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

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

### Authority required (STREAMLINED)

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### Clinical criteria:
The condition must be associated with cytotoxic chemotherapy being used to treat breast cancer,

AND

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

AND

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

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

### Authority required (STREAMLINED)

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

AND

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

AND

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

AND

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

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

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

### Note

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

### Note

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

### Note

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

### PROCHLORPERAZINE

#### Caution

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

#### Note

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

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ALIMENTARY TRACT AND METABOLISM

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BILE AND LIVER THERAPY

**Bile acid preparations**

**URSODEOXYCHOLIC ACID**

**Authority required (STREAMLINED)**

1700

Primary biliary cirrhosis

**Note**

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

**Note**

Continuing Therapy Only:

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

8448P| ursofalk| 2 2 .. | *372.94 | 36.90 | | Ursofalk OA |

DRUGS FOR CONSTIPATION

**Contact laxatives**

**BISACODYL**

*Restricted benefit*

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

*Restricted benefit*

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

*Restricted benefit*

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

*Restricted benefit*
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<td>1104D</td>
<td>rhamnus frangula 80 mg/g + sterculia 620 mg/g granules, 500 g</td>
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Osmotically acting laxatives

LACTULOSE

Restricted benefit
Hepatic coma or precoma (chronic portal-systemic encephalopathy)

Restricted benefit
Constipation in patients with malignant neoplasia

Restricted benefit

Constipation in patients with malignant neoplasia

3064G | LACTULOSE Mixture 3.34 g per 5 mL, 500 mL, 1 | ‡1 5             | ..          | 10.70                          | 11.85    |                                           | Genlac QA                   |

MACROGOL-3350

Restricted benefit
Constipation

Clinical criteria:
Patient must have malignant neoplasia.

Restricted benefit
Constipation

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

AND

The condition must be unresponsive to other oral therapies.

Restricted benefit
Constipation

Clinical criteria:
Patient must have malignant neoplasia.
### Clinical criteria:
Patient must be receiving palliative care.

**Restricted benefit**

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

**Restricted benefit**

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

**Note**

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

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**MACROGOL-3350 + SODIUM CHLORIDE + POTASSIUM CHLORIDE + BICARBONATE**

**Restricted benefit**

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

**Restricted benefit**

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

AND

The condition must be unresponsive to other oral therapies.

**Restricted benefit**

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

**Restricted benefit**

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

### Enemas

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<td>macrogol-3350 13.12 g + sodium chloride 350.7 mg + potassium chloride 46.6 mg (0.63 mmol potassium) + sodium bicarbonate 178.5 mg solution, 30 sachets</td>
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<td>macrogol-3350 13.12 g/25 mL + sodium chloride 350.7 mg/25 mL + potassium chloride 46.6 mg/25 mL (0.63 mmol/25 mL potassium) + sodium bicarbonate 178.5 mg/25 mL oral liquid, 500 mL</td>
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Other drugs for constipation

**GLYCEROL**

Restricted benefit

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

Restricted benefit

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

Restricted benefit

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

Restricted benefit

Patients receiving palliative care

Restricted benefit

Terminal malignant neoplasia

Restricted benefit

Anorectal congenital abnormalities

Restricted benefit

Megacolon

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**ALIMENTARY TRACT AND METABOLISM**

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**ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATORY/ANTIINFECTIVE AGENTS**

### INTESTINAL ANTIINFECTIVES

#### Antibiotics

**NYSTATIN**

- **1699K** nystatin 500 000 international units capsule, 50
- **3345C** nystatin 500 000 international units capsule, 50
- **1696G** nystatin 500 000 international units tablet, 50
- **3342X** nystatin 500 000 international units tablet, 50

**RIFAXIMIN**

**Authority required**

**Prevention of hepatic encephalopathy**

**Clinical criteria:**

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

**Treatment criteria:**

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

**Note**

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

**Note**

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

- **10001J** rifaximin 550 mg tablet, 56

**VANCOMYCIN**

**Authority required**

Antibiotic associated pseudomembranous colitis due to Clostridium difficile which is unresponsive to metronidazole

**Authority required**

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

**Note**

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

- **3113W** vancomycin 125 mg capsule, 20
- **3114X** vancomycin 250 mg capsule, 20

### ELECTROLYTES WITH CARBOHYDRATES

#### Oral rehydration salt formulations

**SODIUM CHLORIDE + POTASSIUM CHLORIDE + GLUCOSE MONOHYDRATE + CITRATE**

**Note**

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

- **3196F** sodium chloride 470 mg + potassium chloride 300 mg + glucose monohydrate 3.56 g + sodium acid citrate 530 mg oral liquid: powder for, 10 x 4.9 g sachets
  - **a** Repalyte New Formulation
  - **a** restore O.R.S.
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**Mesalazine**

**Authority required (STREAMLINED)**

**1708**

Ulcerative colitis where hypersensitivity to sulfonamides exists

**Authority required (STREAMLINED)**

**1709**

Ulcerative colitis where intolerance to sulfasalazine exists

**Note**

Continuing Therapy Only:

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<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>2214M NP</td>
<td>mesalazine 500 mg tablet: modified release, 100 tablets</td>
<td>2</td>
<td>5</td>
<td>..</td>
<td>*297.78</td>
<td>36.90</td>
<td>Pentasa FP</td>
</tr>
</tbody>
</table>

**MESALAZINE**

**Restricted benefit**

Acute episode of mild to moderate ulcerative proctitis

**Note**

Not for the treatment of Crohn disease.

**Note**

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

**Note**

Continuing Therapy Only:

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<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>5461K NP</td>
<td>mesalazine 1 g suppository, 30</td>
<td>1</td>
<td>1</td>
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<td>136.73</td>
<td>36.90</td>
<td>Salofalk OA</td>
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<tr>
<td>8752P NP</td>
<td>mesalazine 1 g suppository, 30</td>
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<td>1</td>
<td>..</td>
<td>136.73</td>
<td>36.90</td>
<td>Pentasa FP</td>
</tr>
</tbody>
</table>

**MESALAZINE**

**Authority required (STREAMLINED)**

1707

Acute episode of mild to moderate ulcerative colitis

**Note**

Not for the treatment of Crohn disease.

**Note**

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

**Note**

Continuing Therapy Only:

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<tr>
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<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>8753Q NP</td>
<td>mesalazine 1 g/100 mL enema, 7 x 100 mL</td>
<td>4</td>
<td>1</td>
<td>..</td>
<td>*336.56</td>
<td>36.90</td>
<td>Pentasa FP</td>
</tr>
<tr>
<td>8768L NP</td>
<td>mesalazine 1 g/application enema, 14 applications</td>
<td>4</td>
<td>1</td>
<td>..</td>
<td>*336.56</td>
<td>36.90</td>
<td>Salofalk OA</td>
</tr>
<tr>
<td>8616L NP</td>
<td>mesalazine 2 g/60 mL enema, 7 x 60 mL</td>
<td>4</td>
<td>1</td>
<td>..</td>
<td>*336.56</td>
<td>36.90</td>
<td>Salofalk OA</td>
</tr>
<tr>
<td>8617M NP</td>
<td>mesalazine 4 g/60 mL enema, 7 x 60 mL</td>
<td>4</td>
<td>1</td>
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</table>

**OLSALAZINE**

**Authority required (STREAMLINED)**

1708

Ulcerative colitis where hypersensitivity to sulfonamides exists

**Authority required (STREAMLINED)**

1709

Ulcerative colitis where intolerance to sulfasalazine exists

**Note**

Not for the treatment of Crohn disease.

**Note**

Continuing Therapy Only:

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<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>1728Y NP</td>
<td>olsalazine sodium 250 mg capsule, 100</td>
<td>1</td>
<td>5</td>
<td>..</td>
<td>61.75</td>
<td>36.90</td>
<td>Dipentum UC</td>
</tr>
<tr>
<td>8086N NP</td>
<td>olsalazine sodium 500 mg tablet, 100</td>
<td>1</td>
<td>5</td>
<td>..</td>
<td>103.63</td>
<td>36.90</td>
<td>Dipentum UC</td>
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</tbody>
</table>

**SULFASALAZINE**

**Note**

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been
**ALIMENTARY TRACT AND METABOLISM**

<table>
<thead>
<tr>
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<th>Name, Restriction, Manner of Administration and Form</th>
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<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>2096H NP</td>
<td>SULFASALAZINE Tablet 500 mg (enteric coated), 100</td>
<td>2</td>
<td>5</td>
<td>..</td>
<td>*54.60</td>
<td>36.90</td>
<td>a Pyralin EN FZ</td>
</tr>
<tr>
<td>2093E NP</td>
<td>sulfasalazine 500 mg tablet, 100</td>
<td>2</td>
<td>5</td>
<td>..</td>
<td>*50.62</td>
<td>36.90</td>
<td>a Salazopyrin-PF</td>
</tr>
</tbody>
</table>

**SULFASALAZINE**

*Restricted benefit*

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

**Note**

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

<table>
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<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
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<th>No. of Rpts</th>
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<tr>
<td>9209Q NP</td>
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<td>11</td>
<td>..</td>
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<td>36.90</td>
<td>a Pyralin EN FZ</td>
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<tr>
<td>9208P NP</td>
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<td>11</td>
<td>..</td>
<td>*50.62</td>
<td>36.90</td>
<td>a Salazopyrin-PF</td>
</tr>
</tbody>
</table>

**DIGESTIVES, INCL. ENZYMES**

**Enzyme preparations**

**PANCREATIC EXTRACT**

*Note*

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</thead>
<tbody>
<tr>
<td>8020D NP</td>
<td>pancreatic extract 10 000 international units capsule: modified release, 100 capsules</td>
<td>5</td>
<td>10</td>
<td>..</td>
<td>*184.01</td>
<td>36.90</td>
<td>Creon 10,000 AB</td>
</tr>
<tr>
<td>8021E NP</td>
<td>pancreatic extract 25 000 international units capsule: modified release, 100 capsules</td>
<td>2</td>
<td>10</td>
<td>..</td>
<td>*148.08</td>
<td>36.90</td>
<td>Creon 25,000 AB</td>
</tr>
<tr>
<td>9412J NP</td>
<td>pancreatic extract 40 000 international units capsule: modified release, 100 capsules</td>
<td>2</td>
<td>10</td>
<td>..</td>
<td>*230.30</td>
<td>36.90</td>
<td>Creon 40,000 AB</td>
</tr>
<tr>
<td>5453B NP</td>
<td>pancreatic extract 5000 international units/100 mg granules: enteric-coated, 20 g</td>
<td>3</td>
<td>10</td>
<td>..</td>
<td>*142.12</td>
<td>36.90</td>
<td>Creon Micro AB</td>
</tr>
</tbody>
</table>

**PANCREATIC EXTRACT**

*Restricted benefit*

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

**Note**

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

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<tr>
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<tr>
<td>9226N NP</td>
<td>pancreatic extract 10 000 international units capsule: modified release, 100 capsules</td>
<td>5</td>
<td>21</td>
<td>..</td>
<td>*184.01</td>
<td>36.90</td>
<td>Creon 10,000 AB</td>
</tr>
<tr>
<td>9227P NP</td>
<td>pancreatic extract 25 000 international units capsule: modified release, 100 capsules</td>
<td>2</td>
<td>21</td>
<td>..</td>
<td>*148.08</td>
<td>36.90</td>
<td>Creon 25,000 AB</td>
</tr>
<tr>
<td>9413K NP</td>
<td>pancreatic extract 40 000 international units capsule: modified release, 100 capsules</td>
<td>2</td>
<td>21</td>
<td>..</td>
<td>*230.30</td>
<td>36.90</td>
<td>Creon 40,000 AB</td>
</tr>
<tr>
<td>5454C NP</td>
<td>pancreatic extract 5000 international units/100 mg granules: enteric-coated, 20 g</td>
<td>3</td>
<td>21</td>
<td>..</td>
<td>*142.12</td>
<td>36.90</td>
<td>Creon Micro AB</td>
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**PANCRELIPASE**

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<tr>
<td>8366H</td>
<td>pancrelipase 25 000 units capsule, 100</td>
<td>2</td>
<td>10</td>
<td>..</td>
<td>*138.24</td>
<td>36.90</td>
<td>Panzytrat 25000</td>
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<td></td>
<td><strong>PANCRELIPASE</strong></td>
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<td></td>
<td>TM</td>
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<td><strong>Restricted benefit</strong></td>
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<tr>
<td></td>
<td>For use in patients with cystic fibrosis, and who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements</td>
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<td><strong>Note</strong></td>
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<td></td>
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<td></td>
<td></td>
</tr>
<tr>
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<td>No applications for increased maximum quantities and/or repeats will be authorised.</td>
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<tr>
<td>9229R</td>
<td>pancrelipase 25 000 units capsule, 100</td>
<td>2</td>
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<td>..</td>
<td>*138.24</td>
<td>36.90</td>
<td>Panzytrat 25000</td>
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</table>

### DRUGS USED IN DIABETES

#### INSULINS AND ANALOGUES

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

**INSULIN ASPART**

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
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<tbody>
<tr>
<td>8571D</td>
<td>insulin aspart 100 international units/mL injection, 1 x 10 mL vial</td>
<td>5</td>
<td>2</td>
<td>..</td>
<td>*159.61</td>
<td>36.90</td>
<td>NovoRapid NO</td>
</tr>
<tr>
<td>8435Y</td>
<td>insulin aspart 100 international units/mL injection, 5 x 3 mL cartridges</td>
<td>5</td>
<td>1</td>
<td>..</td>
<td>*264.56</td>
<td>36.90</td>
<td>NovoRapid FlexPen NF</td>
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**INSULIN GLULISINE**

<table>
<thead>
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<th>Code</th>
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<tbody>
<tr>
<td>9224L</td>
<td>insulin glulisine 100 international units/mL injection, 1 x 10 mL vial</td>
<td>5</td>
<td>2</td>
<td>..</td>
<td>*159.61</td>
<td>36.90</td>
<td>Apidra SW</td>
</tr>
<tr>
<td>1921D</td>
<td>insulin glulisine 100 international units/mL injection, 5 x 3 mL cartridges</td>
<td>5</td>
<td>1</td>
<td>..</td>
<td>*264.56</td>
<td>36.90</td>
<td>Apidra AV</td>
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</table>

**INSULIN LISPRO**

<table>
<thead>
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<th>Code</th>
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<tbody>
<tr>
<td>8084L</td>
<td>insulin lispro 100 international units/mL injection, 1 x 10 mL vial</td>
<td>5</td>
<td>2</td>
<td>..</td>
<td>*159.61</td>
<td>36.90</td>
<td>Humalog LY</td>
</tr>
<tr>
<td>8212F</td>
<td>insulin lispro 100 international units/mL injection, 5 x 3 mL cartridges</td>
<td>5</td>
<td>1</td>
<td>..</td>
<td>*264.56</td>
<td>36.90</td>
<td>Humalog KwikPen KP</td>
</tr>
</tbody>
</table>

**INSULIN NEUTRAL BOVINE**

**Authority required**

Diabetes mellitus

**Clinical criteria:**

Patient must be intolerant to human insulin.

<table>
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<tr>
<th>Code</th>
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</tr>
</thead>
<tbody>
<tr>
<td>1713E</td>
<td>insulin neutral bovine 100 international units/mL injection, 1 x 10 mL vial</td>
<td>5</td>
<td>2</td>
<td>..</td>
<td>*401.06</td>
<td>36.90</td>
<td>Hypurin Neutral AS</td>
</tr>
</tbody>
</table>

**INSULIN NEUTRAL HUMAN**

**Authority required**

Diabetes mellitus

**Clinical criteria:**

Patient must be intolerant to human insulin.

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
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<th>Brand Name and Manufacturer</th>
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<tr>
<td>1531N</td>
<td>insulin neutral human 100 international units/mL injection, 1 x 10 mL vial</td>
<td>5</td>
<td>2</td>
<td>..</td>
<td>*134.16</td>
<td>36.90</td>
<td>Actrapid NO</td>
</tr>
<tr>
<td>1762R</td>
<td>insulin neutral human 100 international units/mL injection, 5 x 3 mL cartridges</td>
<td>5</td>
<td>1</td>
<td>..</td>
<td>*224.66</td>
<td>36.90</td>
<td>Actrapid Penfill 3 mL NO</td>
</tr>
</tbody>
</table>

### Insulins and analogues for injection, intermediate-acting

**INSULIN ISOPHANE BOVINE**

**Authority required**

Diabetes mellitus

**Clinical criteria:**

Patient must be intolerant to human insulin.

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
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</thead>
<tbody>
<tr>
<td>1711C</td>
<td>insulin isophane bovine 100 international units/mL injection, 1 x 10 mL vial</td>
<td>5</td>
<td>2</td>
<td>..</td>
<td>*401.06</td>
<td>36.90</td>
<td>Hypurin Isophane AS</td>
</tr>
<tr>
<td>Code</td>
<td>Name, Restriction, Manner of Administration and Form</td>
<td>Max. Qty (Packs)</td>
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<td>Dispensed Price for Max. Qty $</td>
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<td>Brand Name and Manufacturer</td>
</tr>
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<td>-------------------------------</td>
<td>------------------------------------------</td>
<td>-------------------------------</td>
</tr>
<tr>
<td>1533Q</td>
<td>insulin isophane human 100 international units/mL injection, 1 x 10 mL vial</td>
<td>5</td>
<td>2</td>
<td>..</td>
<td>*134.16</td>
<td>36.90</td>
<td>Humulin NPH LY</td>
</tr>
<tr>
<td>1761Q</td>
<td>insulin isophane human 100 international units/mL injection, 5 x 3 mL cartridges</td>
<td>5</td>
<td>1</td>
<td>..</td>
<td>*224.66</td>
<td>36.90</td>
<td>Protaphane NPH NO</td>
</tr>
<tr>
<td>1761W</td>
<td>insulin isophane human 100 international units/mL injection, 5 x 3 mL cartridges</td>
<td>5</td>
<td>1</td>
<td>..</td>
<td>*224.66</td>
<td>36.90</td>
<td>Protaphane InnoLet NO</td>
</tr>
<tr>
<td>1763T</td>
<td>insulin isophane human 70 international units/mL + insulin neutral human 30 international units/mL injection, 5 x 3 mL cartridges</td>
<td>5</td>
<td>1</td>
<td>..</td>
<td>*224.66</td>
<td>36.90</td>
<td>Humulin 30/70 LY</td>
</tr>
<tr>
<td>1426C</td>
<td>insulin neutral human 30 international units/mL + insulin isophane human 70 international units/mL injection, 1 x 10 mL vial</td>
<td>5</td>
<td>2</td>
<td>..</td>
<td>*134.16</td>
<td>36.90</td>
<td>Humulin 30/70 LY</td>
</tr>
<tr>
<td>2062M</td>
<td>insulin neutral human 50 international units/mL + insulin isophane human 50 international units/mL injection, 5 x 3 mL cartridges</td>
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**Insulins and analogues for injection, intermediate-acting combined with fast-acting**

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

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

**Biguanides**

**METFORMIN**
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* Sulfonamides, urea derivatives

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GLIPIZIDE

Caution

Sulfonylureas may cause hypoglycaemia, particularly in the elderly.

2440K

Glipizide 5 mg tablet, 100

1 5

Dispensed Price for Max. Qty $ 14.47

Premium % $ 2.81

Maximum Recordable Value for Safety Net $ 12.81

Brand Name and Manufacturer

a Glimepiride GA 4 GN

a Glimepiride Sandoz SZ

a Amaryl SW

Combinations of oral blood glucose lowering drugs

ALOGLIPTIN + METFORMIN

Authority required (STREAMLINED)

4423

Diabetes mellitus type 2

Clinical criteria:

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

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

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

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

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

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

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

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

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

Authority required (STREAMLINED)

4427

Diabetes mellitus type 2

Treatment Phase: Continuing

Clinical criteria:

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

Note

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

10035E

Alogliptin 12.5 mg + metformin hydrochloride 1 g tablet, 56

1 5

Dispensed Price for Max. Qty $ 63.26

Premium % $ 36.90

Maximum Recordable Value for Safety Net $ 40.90

Brand Name and Manufacturer

TK Nesina Met 12.5/1000

TK Nesina Met 12.5/500

TK Nesina Met 12.5/850

LINAGLIPTIN + METFORMIN

Authority required (STREAMLINED)

4423

Diabetes mellitus type 2

Clinical criteria:

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

Note

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

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

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

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

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

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

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

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

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

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

**Authority required (STREAMLINED)**

4448
Diabetes mellitus type 2
Treatment Phase: Continuing

Clinical criteria:

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

Note

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

**METFORMIN + GLIBENCLAMIDE**

Caution

Sulfonylureas may cause hypoglycaemia, particularly in the elderly.

**ROSIGLITAZONE + METFORMIN**

Authority required

Diabetes mellitus type 2

Clinical criteria:

Patient must have a contraindication to a sulfonylurea; OR

Patient must not have tolerated a sulfonylurea,

AND

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

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<td>OR</td>
<td>Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with metformin. The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient’s medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated. The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated. Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances: (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or (b) Had red cell transfusion within the previous 3 months. The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient’s medical records. <strong>Note</strong> This fixed dose combination tablet is not PBS-subsidised for use in combination with a sulfonylurea (triple oral therapy), or in combination with a dipeptidyl peptidase 4 inhibitor (gliptin), a glucagon-like peptide-1, an insulin or an SGLT2 inhibitor.</td>
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<td>SAXAGLIPTIN + METFORMIN Authority required (STREAMLINED)</td>
<td>4423 Diabetes mellitus type 2 Clinical criteria: Patient must have, or have had, a HbA1c measurement greater than 7% despite treatment with metformin; OR Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period despite treatment with metformin. The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient’s medical records at the time treatment with a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor is initiated. The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated. Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances: (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or (b) Had red cell transfusion within the previous 3 months. The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient’s medical records. A patient whose diabetes was previously demonstrated unable to be controlled with metformin does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this fixed dose combination. Authority required (STREAMLINED) 4451 Diabetes mellitus type 2</td>
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ALIMENTARY TRACT AND METABOLISM

<table>
<thead>
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<th>Treatment Phase: Continuing</th>
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Clinical criteria:

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

Note

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

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<th>Code</th>
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</tbody>
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SITAGLIPTIN + METFORMIN

Authority required (STREAMLINED)

4423

Diabetes mellitus type 2

Clinical criteria:

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

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

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

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

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

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

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

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

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

Authority required (STREAMLINED)

4309

Diabetes mellitus type 2

Treatment Phase: Continuing

Clinical criteria:

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

Note

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

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<tr>
<th>Code</th>
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<td>Janumet XR</td>
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</table>

MK
## Vildagliptin + Metformin

**Authority required [STREAMLINED]**

### 4423

Diabetes mellitus type 2

**Clinical criteria:**

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

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

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

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

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

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

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

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

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

**Authority required [STREAMLINED]**

### 4308

Diabetes mellitus type 2

**Treatment Phase: Continuing**

**Clinical criteria:**

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

**Note**

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

### 5476F

**NP**

vildagliptin 50 mg + metformin hydrochloride 1 g tablet, 60

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### Alpha glucosidase inhibitors

**ACARBOSE**

acerbade 100 mg tablet, 90

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<th>Code</th>
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### Thiazolidinediones
PIOGLITAZONE

**Authority required (STREAMLINED)**

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</table>

**Clinical criteria:**

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

**AND**

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

**AND**

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

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

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

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

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

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

**Authority required (STREAMLINED)**

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</table>

**Clinical criteria:**

- The treatment must be in combination with insulin,

**AND**

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

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

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

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

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

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

Authority required (STREAMLINED)

4364
Diabetes mellitus type 2

Clinical criteria:

The treatment must be in combination with metformin,

AND

The treatment must be in combination with a sulfonylurea,

AND

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

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

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

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

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

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

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

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

Note

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

<table>
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<td>Patient must have a contraindication to a combination of metformin and a sulfonylurea; OR</td>
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<td>Patient must not have tolerated a combination of metformin and a sulfonylurea,</td>
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<td>Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with either metformin or a sulfonylurea; OR</td>
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<td>Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with either metformin or a sulfonylurea.</td>
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<td>The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient’s medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.</td>
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<td>Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:</td>
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<td>(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or</td>
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<td>(b) Had red cell transfusion within the previous 3 months.</td>
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<td>The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient’s medical records.</td>
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<tr>
<td>Note: This drug is not PBS-subsidised for use in combination with metformin and a sulfonylurea (triple oral therapy), as monotherapy or in combination with a dipeptidyl peptidase 4 inhibitor (gliptin), a glucagon-like peptide-1, an insulin or an SGLT2 inhibitor.</td>
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</table>
## ALIMENTARY TRACT AND METABOLISM

### Dipeptidyl peptidase 4 (DPP-4) inhibitors

#### ALOGLIPTIN

**Authority required (STREAMLINED)**

4349

Diabetes mellitus type 2

**Clinical criteria:**

The treatment must be in combination with metformin; OR

The treatment must be in combination with a sulfonylurea,

**AND**

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

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

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

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

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

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

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

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

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

#### Note

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

<table>
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<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>Dispensed Price for Max. Qty $</th>
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<td>GK</td>
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#### LINAGLIPTIN

**Authority required (STREAMLINED)**

4488

Diabetes mellitus type 2

**Clinical criteria:**

The treatment must be in combination with metformin; OR

The treatment must be in combination with a sulfonylurea,

**AND**

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

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

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient’s medical records at the time treatment with a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor is initiated.
The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

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

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

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

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

SAXAGLIPTIN
Authority required (STREAMLINED)

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

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

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

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

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

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

Note
Saxagliptin is not PBS-subsidised for use in combination with metformin and a sulfonylurea (triple oral therapy), as monotherapy or in combination with a thiazolidinedione (glitazone), a glucagon-like peptide-1 or an SGLT2 inhibitor.
The treatment must be in combination with metformin; OR

**AND**

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

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

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

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

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

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

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

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

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

**Note**

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

**VILDAGLIPTIN**

**Authority required (STREAMLINED)**

4467

Diabetes mellitus type 2

**Clinical criteria:**

The treatment must be in combination with metformin; OR

The treatment must be in combination with a sulfonylurea,

**AND**

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

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

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

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

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

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

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

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

A patient whose diabetes was previously demonstrated unable to be controlled with metformin or a sulfonylurea does not need to requalify on this
Vildagliptin is not PBS-subsidised for use in combination with metformin and a sulfonylurea (triple oral therapy), as monotherapy or in combination with a thiazolidinedione (glitazone), a glucagon-like peptide-1 or an SGLT2 inhibitor.

**Note**

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

### Other blood glucose lowering drugs, excl. insulins

**CANAGLIFLOZIN**

**Authority required**

Diabetes mellitus type 2

**Clinical criteria:**

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

**AND**

- The condition must not be able to be adequately controlled by treatment with metformin and a sulfonylurea,

**AND**

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

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

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

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

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

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

**Note**

**Continuing Therapy Only:**

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

**Note**

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

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

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

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

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

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

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

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

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

EXENATIDE
Authority required (STREAMLINED)
4392
Diabetes mellitus type 2
Clinical criteria:
The treatment must be in combination with metformin; OR
The treatment must be in combination with a sulfonylurea,
AND
Patient must have a contraindication to a combination of metformin and a sulfonylurea; OR
Patient must not have tolerated a combination of metformin and a sulfonylurea,
AND
Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with either metformin or a sulfonylurea; OR
Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with either metformin or a sulfonylurea.

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

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

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

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

**Authority required (STREAMLINED)**

**4405**

Diabetes mellitus type 2

**Clinical criteria:**

The treatment must be in combination with metformin,

AND

The treatment must be in combination with a sulfonylurea,

AND

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

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

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

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

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

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

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

**Note**

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

**Note**

Special Pricing Arrangements apply.

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<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty</th>
<th>No. of Rpts</th>
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<th>Dispensed Price for Max. Qty $</th>
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**VITAMINS**

**VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO**

**Vitamin D and analogues**

**CALCITRIOL**

**Authority required (STREAMLINED)**

**1165**

Hypocalcaemia due to renal disease

**Authority required (STREAMLINED)**

**1166**

Hypoparathyroidism

**Authority required (STREAMLINED)**

**1167**
### ALIMENTARY TRACT AND METABOLISM

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<td><strong>MINERAL SUPPLEMENTS</strong></td>
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<td></td>
<td><strong>CALCIUM</strong></td>
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<tr>
<td></td>
<td><strong>Calcium</strong></td>
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<td>4586</td>
<td>Hyperphosphataemia</td>
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<td></td>
<td><strong>Clinical criteria:</strong></td>
<td></td>
<td></td>
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</tr>
<tr>
<td></td>
<td>The condition must be associated with chronic renal failure.</td>
<td></td>
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<tr>
<td>3116B</td>
<td>CALCIUM Tablet (chewable) 500 mg (as carbonate), 60</td>
<td>4</td>
<td>1</td>
<td>..</td>
<td>*29.24</td>
<td>30.39</td>
<td>a Cal-500 PP</td>
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<td></td>
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<td></td>
<td>a Cal-Sup IA</td>
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<td>3117C</td>
<td>CALCIUM Tablet 600 mg (as carbonate), 240</td>
<td>1</td>
<td>1</td>
<td>..</td>
<td>22.54</td>
<td>23.69</td>
<td>Calci-Tab 600 AE</td>
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<td></td>
<td><strong>POTASSIUM</strong></td>
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<tr>
<td></td>
<td><strong>Potassium</strong></td>
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<tr>
<td></td>
<td><strong>POTASSIUM CHLORIDE</strong></td>
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<tr>
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<td><strong>Note</strong></td>
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<tr>
<td></td>
<td>For item codes 2642C and 1841X, pharmaceutical benefits that have the form tablet 600 mg (sustained release) are equivalent for the purposes of substitution.</td>
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<tr>
<td>2642C</td>
<td>potassium chloride 600 mg (8 mmol potassium) tablet: modified release, 100 tablets</td>
<td>2</td>
<td>1</td>
<td>..</td>
<td>*13.22</td>
<td>14.37</td>
<td>a Duro-K NM</td>
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<tr>
<td>1841X</td>
<td>potassium chloride 600 mg (8 mmol potassium) tablet: modified release, 200 tablets</td>
<td>1</td>
<td>1</td>
<td>..</td>
<td>13.21</td>
<td>14.36</td>
<td>a Slow-K NV</td>
</tr>
<tr>
<td>3012M</td>
<td>potassium chloride 595 mg + potassium</td>
<td>1</td>
<td>1</td>
<td>..</td>
<td>15.48</td>
<td>16.63</td>
<td>Chlorvescent AS</td>
</tr>
</tbody>
</table>

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

**Vitamin B1, plain**

**THIAMINE**

**Authority required (STREAMLINED)**

2384

Prophylaxis of thiamine deficiency in an Aboriginal or a Torres Strait Islander person

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
<th>Premium</th>
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<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
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<td>1070H</td>
<td>thiamine hydrochloride 100 mg tablet, 100</td>
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<td>10.45</td>
<td>11.60</td>
<td>Betavit PP</td>
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<tr>
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<td><strong>POTASSIUM</strong></td>
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<tr>
<td></td>
<td><strong>Potassium</strong></td>
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<tr>
<td></td>
<td><strong>POTASSIUM CHLORIDE + POTASSIUM BICARBONATE</strong></td>
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<tr>
<td></td>
<td><strong>POTASSIUM CHLORIDE + POTASSIUM CARBONATE</strong></td>
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</table>
OTHER MINERAL SUPPLEMENTS

Magnesium

MAGNESIUM ASPARTATE DIHYDRATE

**Authority required**

Hypomagnesaemia in an Aboriginal or a Torres Strait Islander person

**Authority required**

Chronic renal disease in an Aboriginal or a Torres Strait Islander person

<table>
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<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
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<th>No. of Rpts</th>
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<th>Brand Name and Manufacturer</th>
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<tr>
<td>NP</td>
<td>bicarbonate 384 mg + potassium carbonate 152 mg (total potassium 14 mmol) tablet: effervescent. 60</td>
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<td></td>
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<td></td>
</tr>
<tr>
<td>NP</td>
<td>magnesium aspartate dihydrate 500 mg (equivalent to 37.4 mg of magnesium) tablet. 50</td>
<td>1</td>
<td>5</td>
<td>..</td>
<td>14.04</td>
<td>15.19</td>
<td>MagMin (PBS) BB</td>
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</tbody>
</table>

ANABOLIC AGENTS FOR SYSTEMIC USE

ANABOLIC STEROIDS

*Estren derivatives*

NANDROLONE DECANOATE

**Authority required**

Monotherapy for osteoporosis, where other treatment has failed and where specialist advice confirms that this is the only suitable treatment option for the patient. Specialist advice need only be obtained for the first authority approval

**Authority required**

Monotherapy for osteoporosis, where other treatment is not tolerated and where specialist advice confirms that this is the only suitable treatment option for the patient. Specialist advice need only be obtained for the first authority approval

**Authority required**

Monotherapy for osteoporosis, where other treatment is contraindicated and where specialist advice confirms that this is the only suitable treatment option for the patient. Specialist advice need only be obtained for the first authority approval

**Authority required**

Patients receiving PBS-subsidised therapy with this drug for osteoporosis prior to 1 February 2004

**Authority required**

Patients on long-term treatment with corticosteroids

**Note**

Monotherapy for the treatment of osteoporosis does not exclude calcium supplementation.

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
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<th>Premium $</th>
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<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>NP</td>
<td>nandrolone decanoate 50 mg/mL injection, 1 x 1 mL syringe</td>
<td>1</td>
<td>7</td>
<td>..</td>
<td>21.54</td>
<td>22.69</td>
<td>Deca-Durabolin AS</td>
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</tbody>
</table>

OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS

OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS

*Amino acids and derivatives*

BETaine

**Authority required**

Homocystinuria

**Clinical criteria:**

The treatment must be as adjunctive therapy to current standard care,

AND

The condition must be treated by or in consultation with a metabolic physician.

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

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
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<th>Premium $</th>
<th>Dispensed Price for Max. Qty $</th>
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<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>NP</td>
<td>betaine 1 g/g oral liquid: powder for, 180 g</td>
<td>‡1</td>
<td>5</td>
<td>..</td>
<td>570.55</td>
<td>36.90</td>
<td>Cystadane EU</td>
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</tbody>
</table>

Various alimentary tract and metabolism products

SAPROPTERIN

**Authority required**

Hyperphenylalaninaemia

Treatment Phase: Initial
Clinical criteria:
Patient must have hyperphenylalaninaemia (HPA) due to tetrahydrobiopterin (BH4) deficiency.
Patient must have documented tetrahydrobiopterin (BH4) deficiency using tests for BH4 loading and/or urine pterin metabolites, blood spot dihydropteridine reductase (DHPR) and have cerebrospinal fluid neurotransmitter metabolites measured.
The authority application must be made in writing.

Note
Patients will be eligible for a maximum of one script as initial therapy to enable their response to treatment with sapropterin to be assessed.
If a 30% or greater reduction in blood phenylalanine levels is not achieved within one month, the patient is no longer eligible for PBS-subsidised treatment with sapropterin.

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

SAPROPTERIN
Authority required
Hyperphenylalaninaemia
Treatment Phase: Continuing

Clinical criteria:
Patient must have hyperphenylalaninaemia (HPA) due to tetrahydrobiopterin (BH4) deficiency,
AND
Patient must have demonstrated a 30% or greater reduction in blood phenylalanine levels in response to treatment with sapropterin; OR
Patient must have accessed non-PBS-subsidised treatment prior to 1 May 2014.
Patient must have documented tetrahydrobiopterin (BH4) deficiency using tests for BH4 loading and/or urine pterin metabolites, blood spot dihydropteridine reductase (DHPR) and have cerebrospinal fluid neurotransmitter metabolites measured.
The authority application must be made in writing.

Note
Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
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<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>10086W</td>
<td>sapropterin dihydrochloride 100 mg tablet: soluble, 30 tablets</td>
<td>6 ... ...</td>
<td>...</td>
<td>*5306.74</td>
<td>36.90</td>
<td></td>
<td>Kuvan SG</td>
</tr>
<tr>
<td>10087X</td>
<td>sapropterin dihydrochloride 100 mg tablet: soluble, 30 tablets</td>
<td>6 5 ...</td>
<td>...</td>
<td>*5306.74</td>
<td>36.90</td>
<td></td>
<td>Kuvan SG</td>
</tr>
</tbody>
</table>
### ANTITHROMBOTIC AGENTS

**Vitamin K antagonists**

#### WARFARIN

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

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
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<th>Premium $</th>
<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>2843P</td>
<td>warfarin sodium 1 mg tablet, 50</td>
<td>1</td>
<td>2</td>
<td>..</td>
<td>12.75</td>
<td>13.90</td>
<td>Coumadin QA</td>
</tr>
<tr>
<td>2209G</td>
<td>warfarin sodium 2 mg tablet, 50</td>
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<td>2</td>
<td>..</td>
<td>13.11</td>
<td>14.26</td>
<td>Marevan FM</td>
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<tr>
<td>2844Q</td>
<td>warfarin sodium 3 mg tablet, 50</td>
<td>1</td>
<td>2</td>
<td>..</td>
<td>13.03</td>
<td>14.18</td>
<td>Coumadin QA</td>
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<tr>
<td>2211J</td>
<td>warfarin sodium 5 mg tablet, 50</td>
<td>1</td>
<td>2</td>
<td>..</td>
<td>14.37</td>
<td>15.52</td>
<td>Marevan QA</td>
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</table>

#### Heparin group

**DALTEPARIN SODIUM**

**Restricted benefit**

Management of symptomatic venous thromboembolism in a patient with a solid tumour(s)

**Note**
No applications for increased maximum quantities will be authorised.

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
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<tbody>
<tr>
<td>8959M</td>
<td>DALTEPARIN SODIUM (Low Molecular Weight Heparin Sodium-porcine mucous) Injection 15,000 units (anti-Xa) in 0.6 mL single dose pre-filled syringe, 10</td>
<td>3</td>
<td>5</td>
<td>..</td>
<td>*415.09</td>
<td>36.90</td>
<td>Fragmin PF</td>
</tr>
<tr>
<td>8960N</td>
<td>DALTEPARIN SODIUM (Low Molecular Weight Heparin Sodium-porcine mucous) Injection 18,000 units (anti-Xa) in 0.72 mL single dose pre-filled syringe, 10</td>
<td>3</td>
<td>5</td>
<td>..</td>
<td>*493.93</td>
<td>36.90</td>
<td>Fragmin PF</td>
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<tr>
<td>8957K</td>
<td>dalteparin sodium 10 000 anti-Xa international units/mL injection, 10 x 1 mL syringes</td>
<td>3</td>
<td>5</td>
<td>..</td>
<td>*255.40</td>
<td>36.90</td>
<td>Fragmin PF</td>
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<tr>
<td>8958L</td>
<td>dalteparin sodium 12 500 anti-Xa international units/0.5 mL injection, 10 x 0.5 mL syringes</td>
<td>3</td>
<td>5</td>
<td>..</td>
<td>*350.05</td>
<td>36.90</td>
<td>Fragmin PF</td>
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<tr>
<td>8956J</td>
<td>dalteparin sodium 7500 anti-Xa international units/0.75 mL injection, 10 x 0.75 mL syringes</td>
<td>3</td>
<td>5</td>
<td>..</td>
<td>*192.64</td>
<td>36.90</td>
<td>Fragmin PF</td>
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</tbody>
</table>

**DALTEPARIN SODIUM**

**Restricted benefit**

Haemodialysis

<table>
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<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
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<th>Brand Name and Manufacturer</th>
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<tr>
<td>1229Q</td>
<td>dalteparin sodium 10 000 anti-Xa international units/mL injection, 10 x 1 mL syringes</td>
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<td>3</td>
<td>..</td>
<td>*175.90</td>
<td>36.90</td>
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<tr>
<td>1296F</td>
<td>dalteparin sodium 12 500 anti-Xa international units/0.5 mL injection, 10 x 0.5 mL syringes</td>
<td>2</td>
<td>3</td>
<td>..</td>
<td>*241.62</td>
<td>36.90</td>
<td>Fragmin PF</td>
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<tr>
<td>8641T</td>
<td>dalteparin sodium 2500 anti-Xa international units/0.2 mL injection, 10 x 0.2 mL syringes</td>
<td>2</td>
<td>3</td>
<td>..</td>
<td>*105.08</td>
<td>36.90</td>
<td>Fragmin PF</td>
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<tr>
<td>8642W</td>
<td>dalteparin sodium 5000 anti-Xa international units/0.2 mL injection, 10 x 0.2 mL syringes</td>
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<td>3</td>
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<td>*109.22</td>
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<tr>
<td>8643X</td>
<td>dalteparin sodium 7500 anti-Xa international units/0.75 mL injection, 10 x 0.75 mL syringes</td>
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<td>3</td>
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<td>*130.68</td>
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<td>8269F</td>
<td>dalteparin sodium 10 000 anti-Xa international units/mL injection, 10 x 1 mL syringes</td>
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<td>91.33</td>
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<td>5445N</td>
<td>dalteparin sodium 12 500 anti-Xa international units/0.5 mL injection, 10 x 0.5 mL syringes</td>
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<td>1</td>
<td>126.03</td>
<td>36.90</td>
<td>Fragmin PF</td>
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<tr>
<td>8603T</td>
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<td>..</td>
<td>..</td>
<td>36.90</td>
<td>Fragmin PF</td>
<td></td>
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<tr>
<td>2816F</td>
<td>dalteparin sodium 5000 anti-Xa international units/0.2 mL injection, 10 x 0.2 mL syringes</td>
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<td>..</td>
<td>..</td>
<td>36.90</td>
<td>Fragmin PF</td>
<td></td>
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<tr>
<td>8271H</td>
<td>dalteparin sodium 7500 anti-Xa international units/0.75 mL injection, 10 x 0.75 mL syringes</td>
<td>1</td>
<td>1</td>
<td>..</td>
<td>36.90</td>
<td>Fragmin PF</td>
<td></td>
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<tr>
<td></td>
<td><strong>ENOXAPARIN SODIUM</strong></td>
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<tr>
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<td><strong>Restricted benefit</strong></td>
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<tr>
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<td><strong>Haemodialysis</strong></td>
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<tr>
<td>5435C</td>
<td>enoxaparin sodium 100 mg/mL injection, 10 x 1 mL syringes</td>
<td>2</td>
<td>3</td>
<td>211.42</td>
<td>36.90</td>
<td>Clexane SW</td>
<td></td>
</tr>
<tr>
<td>8716R</td>
<td>enoxaparin sodium 20 mg/0.2 mL injection, 10 x 0.2 mL syringes</td>
<td>2</td>
<td>3</td>
<td>105.08</td>
<td>36.90</td>
<td>Clexane SW</td>
<td></td>
</tr>
<tr>
<td>9196B</td>
<td>enoxaparin sodium 40 mg/0.4 mL injection, 10 x 0.4 mL ampoules</td>
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<td>3</td>
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**Platelet aggregation inhibitors excl. heparin**

**ABCIXIMAB**

**Authority required (STREAMLINED)**

1716

Patients undergoing percutaneous coronary balloon angioplasty

**Authority required (STREAMLINED)**

1717

Patients undergoing percutaneous coronary atherectomy

**Authority required (STREAMLINED)**

1718
### BLOOD AND BLOOD FORMING ORGANS

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**CLOPIDOGREL**

**Authority required (STREAMLINED)**

4166

Acute coronary syndrome (myocardial infarction or unstable angina)

**Clinical criteria:**

The treatment must be in combination with aspirin.

**Authority required (STREAMLINED)**

4165

Cardiac stent insertion

**Clinical criteria:**

The treatment must be in combination with aspirin,

AND

The treatment must follow insertion of a cardiac stent.

**Note**

Not for prophylaxis of deep vein thrombosis or peripheral arterial disease.

**Note**

Pharmaceutical benefits that have the forms clopidogrel tablet 75 mg (as besilate) and clopidogrel tablet 75 mg (as hydrogen sulfate) are equivalent for the purposes of substitution.

**Note**

Shared Care Model:

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

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<td>a</td>
<td>Plavix SW</td>
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**CLOPIDOGREL**

**Authority required (STREAMLINED)**

1723

Prevention of recurrence of myocardial infarction or unstable angina in patients where low-dose aspirin poses an unacceptable risk of gastrointestinal bleeding

**Authority required (STREAMLINED)**

1724

Prevention of recurrence of myocardial infarction or unstable angina in patients where there is a history of anaphylaxis, urticaria or asthma within 4 hours of ingestion of aspirin, other salicylates, or NSAIDs

**Authority required (STREAMLINED)**

1719

Prevention of recurrence of ischaemic stroke or transient cerebral ischaemic events in patients with a history of symptomatic cerebrovascular ischaemic episodes while on therapy with low-dose aspirin

**Authority required (STREAMLINED)**

1720

Prevention of recurrence of ischaemic stroke or transient cerebral ischaemic events in patients where low-dose aspirin poses an unacceptable risk of
### Blood and Blood Forming Organs

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| Authority required (STREAMLINED)  
1721 | Prevention of recurrence of ischaemic stroke or transient cerebral ischaemic events in patients where there is a history of anaphylaxis, urticaria or asthma within 4 hours of ingestion of aspirin, other salicylates, or NSAIDs |
| Authority required (STREAMLINED)  
1722 | Prevention of recurrence of myocardial infarction or unstable angina in patients with a history of symptomatic cardiac ischaemic events while on therapy with low-dose aspirin |
| Note | Not for prophylaxis of DVT or peripheral arterial disease. |
| Note | Pharmaceutical benefits that have the forms clopidogrel tablet 75 mg, clopidogrel tablet 75 mg (as besilate) and clopidogrel tablet 75 mg (as hydrogen sulfate) are equivalent for the purposes of substitution. |
| Note | Shared Care Model: For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners. |

| 5436D  
NP  | clopidogrel 75 mg tablet, 28 | 1 | 5 | . | 21.01 | 22.16 | Clopidogrel-DRLA RZ |
| 8358X  
NP  | clopidogrel 75 mg tablet, 28 | 1 | 5 | . | 21.01 | 22.16 | APO-Clopidogrel TX |

### Clopidogrel

**Authority required (STREAMLINED)  
1719**  
Prevention of recurrence of ischaemic stroke or transient cerebral ischaemic events in patients with a history of symptomatic cerebrovascular ischaemic episodes while on therapy with low-dose aspirin

**Authority required (STREAMLINED)  
1720**  
Prevention of recurrence of ischaemic stroke or transient cerebral ischaemic events in patients where low-dose aspirin poses an unacceptable risk of gastrointestinal bleeding

**Authority required (STREAMLINED)  
1721**  
Prevention of recurrence of ischaemic stroke or transient cerebral ischaemic events in patients where there is a history of anaphylaxis, urticaria or asthma within 4 hours of ingestion of aspirin, other salicylates, or NSAIDs

**Authority required (STREAMLINED)  
1722**  
Prevention of recurrence of myocardial infarction or unstable angina in patients with a history of symptomatic cardiac ischaemic events while on therapy with low-dose aspirin

**Authority required (STREAMLINED)  
1723**  
Prevention of recurrence of myocardial infarction or unstable angina in patients where low-dose aspirin poses an unacceptable risk of gastrointestinal bleeding

**Authority required (STREAMLINED)  
1724**  
Prevention of recurrence of myocardial infarction or unstable angina in patients where there is a history of anaphylaxis, urticaria or asthma within 4 hours of ingestion of aspirin, other salicylates, or NSAIDs

**Note**  
Not for prophylaxis of DVT or peripheral arterial disease.
Pharmaceutical benefits that have the forms clopidogrel tablet 75 mg, clopidogrel tablet 75 mg (as besilate) and clopidogrel tablet 75 mg (as hydrogen sulfate) are equivalent for the purposes of substitution.

**Note**

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

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**DIPYRIDAMOLE**

**Restricted benefit**

Prevention of recurrence of ischaemic stroke or transient cerebral ischaemic events as adjunctive therapy with low-dose aspirin

**Restricted benefit**

Prevention of recurrence of ischaemic stroke or transient cerebral ischaemic events where low-dose aspirin poses an unacceptable risk of gastrointestinal bleeding

**Restricted benefit**

Prevention of recurrence of ischaemic stroke or transient cerebral ischaemic events where there is a history of anaphylaxis, urticaria or asthma within 4 hours of ingestion of aspirin, other salicylates, or NSAIDs

**Note**

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

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**Note**
Shared Care Model:

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

### EPTIFIBATIDE

**Authority required (STREAMLINED)**

1884

Patients undergoing non-urgent percutaneous intervention with intracoronary stenting.

### PRASUGREL

**Authority required (STREAMLINED)**

3208

Treatment of acute coronary syndrome (myocardial infarction or unstable angina) managed by percutaneous coronary intervention in combination with aspirin.

**Note**

Shared Care Model:

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

### TICAGRELOR

**Authority required (STREAMLINED)**

3879

Treatment of acute coronary syndrome (myocardial infarction or unstable angina) in combination with aspirin.

**Note**

Shared Care Model:

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

### TICLOPIDINE

**Authority required (STREAMLINED)**

1719

Prevention of recurrence of ischaemic stroke or transient cerebral ischaemic events in patients with a history of symptomatic cerebrovascular ischaemic episodes while on therapy with low-dose aspirin.

**Authority required (STREAMLINED)**

1720

Prevention of recurrence of ischaemic stroke or transient cerebral ischaemic events in patients where low-dose aspirin poses an unacceptable risk of gastrointestinal bleeding.

**Authority required (STREAMLINED)**

1721

Prevention of recurrence of ischaemic stroke or transient cerebral ischaemic events in patients where there is a history of anaphylaxis, urticaria or asthma within 4 hours of ingestion of aspirin, other salicylates, or NSAIDs.

**Authority required (STREAMLINED)**

1260

Patients established on this drug as a pharmaceutical benefit prior to 1 November 1999.

**Caution**

Severe neutropenia is common in the early months of therapy. Haematological monitoring should be undertaken at commencement and every two weeks in the first four months of therapy.

**Note**

Shared Care Model:
### BLOOD AND BLOOD FORMING ORGANS

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<thead>
<tr>
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<td>Patients with high risk unstable angina who have new transient or persistent ST-T ischaemic changes and anginal pain lasting longer than 20 minutes</td>
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Prevention of stroke or systemic embolism

Clinical criteria:

Patient must have non-valvular atrial fibrillation, AND

Patient must have one or more risk factors for developing stroke or systemic embolism.

Risk factors for developing stroke or systemic ischaemic embolism are:

(i) Prior stroke (ischaemic or unknown type), transient ischaemic attack or non-central nervous system (CNS) systemic embolism;
(ii) age 75 years or older;
(iii) hypertension;
(iv) diabetes mellitus;
(v) heart failure and/or left ventricular ejection fraction 35% or less.

Note Shared Care Model:

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

Note

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

Note

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

Note

Special Pricing Arrangements apply.

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DABIGATRAN

Authority required (STREAMLINED)

4402

Prevention of venous thromboembolism

Clinical criteria:

Patient must require up to 30 days supply to complete a course of treatment.

Treatment criteria:

Patient must be undergoing total hip replacement.

Note

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

Note

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

Note

Shared Care Model:

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

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DABIGATRAN

Authority required (STREAMLINED)

4369

Prevention of venous thromboembolism

Clinical criteria:

Patient must require up to 20 days supply to complete a course of treatment.

Treatment criteria:

Patient must be undergoing total hip replacement.

Note

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

**Authority required (STREAMLINED)**

4381

Prevention of venous thromboembolism

**Clinical criteria:**

Patient must require up to 10 days of therapy.

**Treatment criteria:**

Patient must be undergoing total knee replacement.

**Note**

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

**Note**

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

**Note**

Shared Care Model:

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

**Direct factor Xa inhibitors**

**APIXABAN**

**Authority required (STREAMLINED)**

4381

Prevention of venous thromboembolism

**Clinical criteria:**

Patient must require up to 10 days of therapy.

**Treatment criteria:**

Patient must be undergoing total knee replacement.

**Authority required (STREAMLINED)**

4359

Prevention of venous thromboembolism

**Clinical criteria:**

Patient must require up to 10 days supply to complete a course of treatment.

**Treatment criteria:**

Patient must be undergoing total hip replacement.

**Note**

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

**Note**

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

**Note**

Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.
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<td>AND</td>
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**APIXABAN**
### Authority required (STREAMLINED)

**4402**
Prevention of venous thromboembolism

**Clinical criteria:**
- Patient must require up to 30 days supply to complete a course of treatment.

**Treatment criteria:**
- Patient must be undergoing total hip replacement.

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

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

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

#### RIVAROXABAN

#### Authority required (STREAMLINED)

**4402**
Prevention of venous thromboembolism

**Clinical criteria:**
- Patient must require up to 30 days supply to complete a course of treatment.

**Treatment criteria:**
- Patient must be undergoing total hip replacement.

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

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

**Note**
- Shared Care Model:
  - For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.
## BLOOD AND BLOOD FORMING ORGANS

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<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>2691P</td>
<td>rivaroxaban 15 mg tablet, 28</td>
<td>1</td>
<td>5</td>
<td>..</td>
<td>94.85</td>
<td>36.90</td>
<td>Xarelto</td>
</tr>
</tbody>
</table>

RIVAROXABAN  
**Authority required (STREAMLINED)**  
4098  
Deep vein thrombosis  
Treatment Phase: Initial treatment  
**Clinical criteria:**  
Patient must have confirmed acute symptomatic deep vein thrombosis,  
AND  
Patient must not have symptomatic pulmonary embolism.  
**Note**  
Shared Care Model:  
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.  
**Note**  
No increase in the maximum quantity or number of units may be authorised.  
**Note**  
No increase in the maximum number of repeats may be authorised.  
**Note**  
Special Pricing Arrangements apply.

<table>
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<tr>
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<tr>
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<td>rivaroxaban 15 mg tablet, 42</td>
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RIVAROXABAN  
**Authority required (STREAMLINED)**  
4099  
Deep vein thrombosis  
Treatment Phase: Continuing treatment  
**Clinical criteria:**  
Patient must have confirmed acute symptomatic deep vein thrombosis,  
AND  
Patient must not have symptomatic pulmonary embolism.  
**Note**  
Shared Care Model:  
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.  
**Note**  
No increase in the maximum quantity or number of units may be authorised.  
**Note**  
No increase in the maximum number of repeats may be authorised.  
**Note**  
Special Pricing Arrangements apply.
**Prevention of recurrent venous thromboembolism**

**Treatment Phase:** Continuing treatment

**Clinical criteria:**
Patient must have a history of venous thromboembolism.

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

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

**Authority required (STREAMLINED)**
4132
Prevention of recurrent venous thromboembolism

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

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

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

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

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

**Prevention of stroke or systemic embolism**

**Clinical criteria:**
Patient must have non-valvular atrial fibrillation, AND
Patient must have one or more risk factors for developing stroke or systemic embolism.

**Risk factors for developing stroke or systemic ischaemic embolism are:**
(i) Prior stroke (ischaemic or unknown type), transient ischaemic attack or non-central nervous system (CNS) systemic embolism;
(ii) age 75 years or older;
(iii) hypertension;
(iv) diabetes mellitus;
(v) heart failure and/or left ventricular ejection fraction 35% or less.

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

<table>
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<td>36.90</td>
<td>Xarelto BN</td>
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**Other antithrombotic agents**

**FONDAPARINUX**

**Authority required (STREAMLINED)**

2005
Prevention of venous thromboembolic events in patients undergoing major hip surgery

**Authority required (STREAMLINED)**

2006
Prevention of venous thromboembolic events in patients undergoing total knee replacement

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

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

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<td>8775W</td>
<td>FONDAPARINUX SODIUM Injection 2.5 mg in 0.5 mL single dose pre-filled syringe, 2</td>
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<td>..</td>
<td>..</td>
<td>*140.88</td>
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**ANTIHEMORRHAGICS**

**ANTIFIBRINOLYTICS**

**Amino acids**

**TRANEXAMIC ACID**

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

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<td>tranexamic acid 500 mg tablet, 100</td>
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<td>52.02</td>
<td>36.90</td>
<td>Cyklokapron PF</td>
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**ANTIHEMORRHAGICS**

**IRON PREPARATIONS**

**Iron bivalent, oral preparations**

**FERROUS FUMARATE**
ferrous fumarate 200 mg (equivalent to 65.7 mg of elemental iron) tablet, 60

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<td>8985X</td>
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<td>1</td>
<td>..</td>
<td>11.96</td>
<td>13.11</td>
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**FERROUS SULFATE**
ferrous sulfate 30 mg/mL (equivalent to 6 mg/mL elemental iron) oral liquid, 250 mL

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<td>2</td>
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<td>19.69</td>
<td>20.84</td>
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**Iron trivalent, parenteral preparations**

**IRON**
iron (as ferric carboxymaltose) 500 mg/10 mL injection, 1 x 10 mL vial

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<tbody>
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<td>10104T</td>
<td>iron (as ferric carboxymaltose)</td>
<td>2</td>
<td>1</td>
<td>..</td>
<td>*317.22</td>
<td>36.90</td>
<td>ferinject VL</td>
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**IRON POLYMALTOSE**
iron (as polymaltose) 100 mg/2 mL injection, 5 x 2 mL ampoules

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<td>2593L</td>
<td>iron (as polymaltose) 100 mg/2 mL</td>
<td>1</td>
<td>..</td>
<td>..</td>
<td>38.91</td>
<td>36.90</td>
<td>a Ferrosig SI</td>
</tr>
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**IRON POLYMALTOSE**
Authority required (STREAMLINED)
4302
Iron deficiency anaemia
### BLOOD AND BLOOD FORMING ORGANS

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</table>

**Treatment criteria:**
- Patient must be undergoing chronic haemodialysis.

**IRON SUCROSE**

**Authority required (STREAMLINED)**

**4292**
- Iron deficiency anaemia

**Clinical criteria:**
- The treatment must be in combination with an erythropoiesis stimulating agent,
- AND
- Patient must have had a documented hypersensitivity reaction to iron polymaltose,
- AND
- Patient must be a person in whom continued intravenous iron therapy is appropriate.

**Iron in combination with folic acid**

**FERROUS FUMARATE + FOLIC ACID**

**9011G**
- Ferrous fumarate 310 mg (equivalent to 100 mg elemental iron) + folic acid 350 microgram tablet, 60

**VITAMIN B12 AND FOLIC ACID**

**Vitamin B12 (cyanocobalamin and analogues)**

**HYDROXOCOBALAMIN**

**Restricted benefit**
- Pernicious anaemia

**Restricted benefit**
- Proven vitamin B12 deficiencies other than pernicious anaemia

**Restricted benefit**
- Anaemias associated with vitamin B12 deficiency

**Clinical criteria:**
- Patient must have had a gastrectomy,
- AND
- The treatment must be for prophylaxis.

**Note**
- One injection of hydroxocobalamin 1 mg every three months provides appropriate maintenance therapy in vitamin B12 deficiencies.

**Note**
- Pharmaceutical benefits that have the form hydroxocobalamin injection 1 mg (as acetate) in 1 mL and pharmaceutical benefits that have the form hydroxocobalamin injection 1 mg (as chloride) in 1 mL are equivalent for the purposes of substitution.

**Folic acid and derivatives**

**FOLIC ACID**

**Note**
- The 5 mg strength tablet should be used in malabsorption states only.

**FOLIC ACID**

**1437P**
- Folic acid 5 mg tablet, 100

**2958Q**
- Folic acid 500 microgram tablet, 100
### BLOOD AND BLOOD FORMING ORGANS

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<td>(Packs)</td>
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<td>NP</td>
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</table>

### BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS

#### Blood substitutes and plasma protein fractions

**GELATIN-SUCCINYLATED**

8444K NP gelatin-succinylated 20 g/500 mL injection, 1 x 500 mL bag 3 .. .. *46.09 36.90 Gelofusine BR

**PENTASTARCH + SODIUM CHLORIDE**

9487H NP HYDROXYETHYL STARCH 130/0.4 I.V. infusion 30 g per 500 mL, 500 mL, 1 3 .. .. *46.09 36.90 Voluven 6% PK

#### I.V. SOLUTIONS

**Solutions for parenteral nutrition**

**GLUCOSE**

2245E NP glucose 5% (50 g/1000 mL) injection, 1 x 1000 mL bag 5 1 .. .. *17.11 18.26 Baxter Healthcare Pty Ltd BX

5106R DP glucose 5% (50 g/1000 mL) injection, 1 x 1000 mL bag 5 .. .. .. *17.11 18.26 Baxter Healthcare Pty Ltd BX

#### Solutions affecting the electrolyte balance

**LACTATE + SODIUM CHLORIDE + POTASSIUM CHLORIDE + CALCIUM CHLORIDE DIHYDRATE**

2286H NP lactate sodium 0.322% (3.22 g/1000 mL) + sodium chloride 0.6% (6 g/1000 mL) + potassium chloride 0.04% (400 mg/1000 mL) + calcium chloride dihydrate 0.027% (270 mg/1000 mL) injection, 1 x 1000 mL bag 5 1 .. .. *15.86 17.01 Baxter Healthcare Pty Ltd BX

**SODIUM CHLORIDE**

2264E NP sodium chloride 0.9% (9 g/1000 mL) injection, 1 x 1000 mL bag 5 1 .. .. *15.21 16.36 Baxter Healthcare Pty Ltd BX

5212H NP sodium chloride 0.9% (9 g/1000 mL) injection, 1 x 1000 mL bag 5 .. .. .. *15.21 16.36 Baxter Healthcare Pty Ltd BX

2260Y NP sodium chloride 3% (30 g/1000 mL) injection, 1 x 1000 mL bag 2 1 .. .. *11.88 13.03 Baxter Healthcare Pty Ltd BX

5213J NP sodium chloride 3% (30 g/1000 mL) injection, 1 x 1000 mL bag 2 .. .. .. *11.88 13.03 Baxter Healthcare Pty Ltd BX

**SODIUM CHLORIDE + GLUTOSE**

2281C NP sodium chloride 0.18% (1.8 g/1000 mL) + glucose 4% (40 g/1000 mL) injection, 1 x 1000 mL bag 5 1 .. .. *23.86 25.01 Baxter Healthcare Pty Ltd BX

5214K DP sodium chloride 0.18% (1.8 g/1000 mL) + glucose 4% (40 g/1000 mL) injection, 1 x 1000 mL bag 5 .. .. .. *23.86 25.01 Baxter Healthcare Pty Ltd BX

2279Y NP sodium chloride 0.225% (1.125 g/500 mL) + glucose 3.75% (18.75 g/500 mL) injection, 1 x 500 mL bag 5 1 .. .. *29.11 30.26 Baxter Healthcare Pty Ltd BX

5215L DP sodium chloride 0.225% (1.125 g/500 mL) + glucose 3.75% (18.75 g/500 mL) injection, 1 x 500 mL bag 5 .. .. .. *29.11 30.26 Baxter Healthcare Pty Ltd BX

2278X NP sodium chloride 0.45% (2.25 g/500 mL) + glucose 2.5% (12.5 g/500 mL) injection, 1 x 500 mL bag 5 1 .. .. *29.11 30.26 Baxter Healthcare Pty Ltd BX

5216M DP sodium chloride 0.45% (2.25 g/500 mL) + glucose 2.5% (12.5 g/500 mL) injection, 1 x 500 mL bag 5 .. .. .. *29.11 30.26 Baxter Healthcare Pty Ltd BX

**SODIUM CHLORIDE + POTASSIUM CHLORIDE + CALCIUM CHLORIDE DIHYDRATE**

2266G NP sodium chloride 8.6 g/1000 mL + potassium chloride 300 mg/1000 mL + calcium chloride dihydrate 330 mg/1000 mL injection, 1 x 1000 mL bag 4 1 .. .. *30.36 31.51 Baxter Healthcare Pty Ltd BX
BLOOD AND BLOOD FORMING ORGANS

SODIUM GLUCONATE + SODIUM CHLORIDE + POTASSIUM CHLORIDE + MAGNESIUM CHLORIDE + SODIUM ACETATE TRIHYDRATE + GLUCOSE

<table>
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<tr>
<th>Code</th>
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<tr>
<td>3199J</td>
<td>sodium gluconate 5.02 g/1000 mL + sodium chloride 5.26 g/1000 mL + potassium chloride 370 mg/1000 mL + magnesium chloride 300 mg/1000 mL + sodium acetate trihydrate 3.68 g/1000 mL + glucose 5% (50 g/1000 mL) injection, 1 x 1000 mL bag</td>
<td>2</td>
<td>1</td>
<td>..</td>
<td>*22.30</td>
<td>23.45</td>
<td>Plasma-Lyte 148 BX</td>
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OTHER HEMATOLOGICAL AGENTS

OTHER HEMATOLOGICAL AGENTS

Drugs used in hereditary angioedema

ICATIBANT

Authority required

Initial supply for anticipated emergency treatment of an acute attack of hereditary angioedema in a patient with confirmed diagnosis of C1-esterase inhibitor deficiency who has been assessed to be at significant risk of an acute attack of hereditary angioedema by or in consultation with a clinical immunologist, respiratory physician, specialist allergist or general physician experienced in the management of patients with hereditary angioedema.

The name of the specialist consulted must be provided at the time of application for initial supply.

The name of the Approved Pathology Authority and date of the diagnosing pathology test must be included in the authority application

Authority required

Continuing supply for anticipated emergency treatment of an acute attack of hereditary angioedema, where the patient has previously been issued with an authority prescription for this drug

Note

Icatibant should be provided in the framework of a comprehensive hereditary angioedema prophylaxis program and an emergency Action Plan including training in recognition of the symptoms of hereditary angioedema and the self-administration of icatibant. (For further information see the Australasian Society of Clinical Immunology and Allergy website at www.allergy.org.au)

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<td>1976B</td>
<td>ICATIBANT Injection 30 mg (as acetate) in 3 mL single use pre-filled syringe, 1</td>
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<td>1</td>
<td>..</td>
<td>2571.70</td>
<td>36.90</td>
<td>Firazyr ZI</td>
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# CARDIOVASCULAR SYSTEM

## CARDIAC THERAPY

### CARDIAC GLYCOSIDES

*Digitalis glycosides*

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<td>1322N</td>
<td>digoxin 250 microgram tablet, 100</td>
<td>1</td>
<td>1</td>
<td>..</td>
<td>11.05</td>
<td>12.20</td>
<td>a Sigmaxin FM</td>
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<tr>
<td>3164M</td>
<td>digoxin 50 microgram/mL oral liquid, 60 mL</td>
<td>2</td>
<td>3</td>
<td>..</td>
<td>*2.94</td>
<td>13.99</td>
<td>12.20 a Lanoxin QA</td>
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<tr>
<td>2605D</td>
<td>digoxin 62.5 microgram tablet, 200</td>
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<td>10.76</td>
<td>11.91</td>
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### ANTIARRHYTHMICS, CLASS I AND III

#### Antiarrhythmics, class Ia

### DISOPYRAMIDE

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<td>46.85</td>
<td>36.90</td>
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#### Antiarrhythmics, class Ib

### LIGNOCAINE

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<tr>
<td>2875H</td>
<td>lignocaine hydrochloride anhydrous 2% (100 mg/5 mL Injection, 5 x 5 mL ampoules)</td>
<td>1</td>
<td>..</td>
<td>..</td>
<td>37.67</td>
<td>36.90</td>
<td>Pfizer Australia Pty Ltd PF</td>
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<tr>
<td>2876J</td>
<td>lignocaine hydrochloride anhydrous 500 mg/5 mL injection, 10 x 5 mL ampoules</td>
<td>1</td>
<td>..</td>
<td>..</td>
<td>29.93</td>
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### Antiarrhythmics, class Ic

### FLECAINIDE

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<td>..</td>
<td>37.67</td>
<td>36.90</td>
<td>Pfizer Australia Pty Ltd PF</td>
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#### Notes

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

*Note:* Digoxin acetate should be avoided in patients with poor cardiac function.
### Antiarrhythmics, class III

**AMIODARONE**

**Restricted benefit**

Severe cardiac arrhythmias

**Caution**

Amiodarone hydrochloride has been reported to cause frequent and potentially serious toxicity.

Regular monitoring of hepatic and thyroid function is recommended.

**Note**

Shared Care Model:

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

### SOTALOL

**Restricted benefit**

Severe cardiac arrhythmias

**Note**

Shared Care Model:

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

### CARDIAC STIMULANTS EXCL. CARDIAC GLYCOSIDES

**Adrenergic and dopaminergic agents**

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>Dispensed Price for Max. Qty $</th>
<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1090J</td>
<td>flecainide acetate 100 mg tablet, 60</td>
<td>1</td>
<td>5</td>
<td>..</td>
<td>45.03</td>
<td>36.90</td>
<td>a Flecatab AF</td>
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<td>1088G</td>
<td>flecainide acetate 50 mg tablet, 60</td>
<td>1</td>
<td>5</td>
<td>..</td>
<td>38.07</td>
<td>36.90</td>
<td>a Tambocor IA</td>
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<tr>
<td>2344J</td>
<td>amiodarone hydrochloride 100 mg tablet, 30</td>
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<td>5</td>
<td>..</td>
<td>12.42</td>
<td>13.57</td>
<td>a Aratac 100 AF</td>
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<td>2343H</td>
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<td>1</td>
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<td>16.83</td>
<td>17.98</td>
<td>a Amiodarone Sandoz SZ</td>
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<tr>
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<td>..</td>
<td>16.98</td>
<td>18.13</td>
<td>a APO-Sotalol TX</td>
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<td>..</td>
<td>11.52</td>
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**ADRENALINE**

<table>
<thead>
<tr>
<th>Code</th>
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<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>1016L</td>
<td>adrenaline 1 in 1000 (1 mg/mL) injection, 5 x 1 mL ampoules</td>
<td>1</td>
<td>1</td>
<td>..</td>
<td>20.68</td>
<td>21.83</td>
<td>Link Medical Products Pty Ltd LM</td>
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<tr>
<td>5004J</td>
<td>adrenaline 1 in 1000 (1 mg/mL) injection, 5 x 1 mL ampoules</td>
<td>1</td>
<td>..</td>
<td>..</td>
<td>20.68</td>
<td>21.83</td>
<td>Link Medical Products Pty Ltd LM</td>
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</tbody>
</table>
ADRENALINE

Authority required

Initial sole PBS-subsidised supply for anticipated emergency treatment of acute allergic reactions with anaphylaxis in a patient who has been assessed to be at significant risk of anaphylaxis by, or in consultation with, a clinical immunologist, allergist, paediatrician or respiratory physician.

The name of the specialist consulted must be provided at the time of application for initial supply

Authority required

Initial sole PBS-subsidised supply for anticipated emergency treatment of acute allergic reactions with anaphylaxis in a patient who has been discharged from hospital or an emergency department after treatment with adrenaline for acute allergic reaction with anaphylaxis

Authority required

Continuing sole PBS-subsidised supply for anticipated emergency treatment of acute allergic reactions with anaphylaxis, where the patient has previously been issued with an authority prescription for this drug

Caution

EpiPen and Anapen products have different administration techniques and should not be prescribed to the same patient without training in their use.

Note

The auto-injector should be provided in the framework of a comprehensive anaphylaxis prevention program and an emergency action plan including training in recognition of the symptoms of anaphylaxis and the use of the auto-injector device. (For further information see the Australasian Society of Clinical Immunology and Allergy website at www.allergy.org.au.)

Note

Authority approvals will be limited to a maximum quantity of 2 auto-injectors (Anapen or EpiPen) at any one time.

No repeats will be issued.

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
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<tr>
<td>3408J</td>
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<td>106.34</td>
<td>36.90</td>
<td>36.90</td>
<td>Anapen Junior LM</td>
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<td>EpiPen Jr. AL</td>
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<td>106.34</td>
<td>36.90</td>
<td>36.90</td>
<td>Anapen LM</td>
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<td>8698T</td>
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<td>36.90</td>
<td>36.90</td>
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VASODILATORS USED IN CARDIAC DISEASES

Organic nitrates

GLYCERYL TRINITRATE

1516T  
glyceryl trinitrate 10 mg/24 hours patch, 30

8011P  
glyceryl trinitrate 10 mg/24 hours patch, 30

8028M  
glyceryl trinitrate 10 mg/24 hours patch, 30

8026K  
glyceryl trinitrate 15 mg/24 hours patch, 30

8119H  
glyceryl trinitrate 15 mg/24 hours patch, 30

1515R  
glyceryl trinitrate 5 mg/24 hours patch, 30

8010N  
glyceryl trinitrate 5 mg/24 hours patch, 30

8027L  
glyceryl trinitrate 5 mg/24 hours patch, 30

1459T  
glyceryl trinitrate 600 microgram tablet: sublingual, 100 tablets

5108W  
glyceryl trinitrate 600 microgram tablet: sublingual, 100 tablets

GLYCERYL TRINITRATE

Note

The spray should not be inhaled.

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<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
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<tr>
<td>8171C</td>
<td>glyceryl trinitrate 400 microgram/actuation spray, 200 actuations</td>
<td>✠1</td>
<td>5</td>
<td>20.47</td>
<td>16.32</td>
<td>16.32</td>
<td>Nitrolingual Pumpspray SW</td>
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**CARDIOVASCULAR SYSTEM**

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<th>Brand Name and Manufacturer</th>
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<td>18.39</td>
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<td>4023</td>
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<td>1822X</td>
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<td>5</td>
<td>..</td>
<td>62.96</td>
<td>36.90</td>
<td>Pexsig QA</td>
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<td>1822</td>
<td><strong>OTHER CARDIAC PREPARATIONS</strong></td>
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<tr>
<td></td>
<td>Other cardiac preparations</td>
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<td><strong>IVABRADINE</strong></td>
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<tr>
<td>124</td>
<td>Chronic heart failure</td>
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<tr>
<td></td>
<td>Patient must be symptomatic with NYHA classes II or III,</td>
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<tr>
<td></td>
<td>Patient must be in sinus rhythm,</td>
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<td></td>
<td><strong>AND</strong></td>
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<tr>
<td></td>
<td>Patient must have a documented left ventricular ejection fraction (LVEF) of less than or equal to 35%,</td>
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<td><strong>AND</strong></td>
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<tr>
<td></td>
<td>Patient must have a resting heart rate at or above 77 bpm at the time ivabradine treatment is initiated,</td>
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<td><strong>AND</strong></td>
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<tr>
<td></td>
<td>Patient must receive concomitant optimal standard chronic heart failure treatment, which must include the maximum tolerated dose of a beta-blocker, unless contraindicated or not tolerated.</td>
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</tbody>
</table>
Resting heart rate should be measured by ECG after 5 minutes rest. The ECG result must be documented in the patient’s medical records when treatment is initiated.

### Note

**Continuing Therapy Only:**

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

### ANTIHYPERTENSIVES

#### ANTIADRENERGIC AGENTS, CENTRALLY ACTING

##### Methyldopa

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<thead>
<tr>
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<th>Name, Restriction, Manner of Administration and Form</th>
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<th>Premium $</th>
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<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>1629R</td>
<td>methyldopa 250 mg tablet, 100</td>
<td>1</td>
<td>5</td>
<td>..</td>
<td>14.21</td>
<td>15.36</td>
<td>Hydopa AF</td>
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<td></td>
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<td></td>
<td></td>
<td></td>
<td>3.54</td>
<td>17.75</td>
<td>Aldomet AS</td>
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##### Imidazoline receptor agonists

<table>
<thead>
<tr>
<th>Code</th>
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<th>Max. Qty (Packs)</th>
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<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
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<td>3145M</td>
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<td>29.22</td>
<td>30.37</td>
<td>Catapres BY</td>
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<tr>
<td>3141H</td>
<td>clonidine hydrochloride 150 microgram tablet, 100</td>
<td>1</td>
<td>5</td>
<td>..</td>
<td>37.78</td>
<td>36.90</td>
<td>Catapres BY</td>
</tr>
</tbody>
</table>

##### Moxonidine

*Restricted benefit*

Hypertension in patients receiving concurrent antihypertensive therapy

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
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<td>19.87</td>
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<tr>
<td>9020R</td>
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<td>5</td>
<td>..</td>
<td>29.12</td>
<td>30.27</td>
<td>Physiotens AB</td>
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</table>

#### ANTIADRENERGIC AGENTS, PERIPHERALLY ACTING

##### Alpha-adrenoreceptor antagonists

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<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
<th>Premium $</th>
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<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
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<tr>
<td>1479W</td>
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<td>5</td>
<td>..</td>
<td>11.71</td>
<td>12.86</td>
<td>APO-Prazosin TX</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>a Chem mart Prazosin CH</td>
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<td></td>
<td></td>
<td></td>
<td>a Minipress PF</td>
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<td>a Chem mart Prazosin CH</td>
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</thead>
<tbody>
<tr>
<td>1478T</td>
<td>prazosin 5 mg tablet, 100</td>
<td>1</td>
<td>5</td>
<td>..</td>
<td>20.91</td>
<td>22.06</td>
<td>APO-Prazosin TX</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>a Chem mart Prazosin CH</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>a Minipress PF</td>
<td></td>
<td></td>
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<tr>
<td></td>
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<td></td>
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<td>a Terry White Chemists Prazosin TW</td>
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</table>

#### ARTERIOLAR SMOOTH MUSCLE, AGENTS ACTING ON

##### Hydrazinophthalazine derivatives

<table>
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<tr>
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<td>1640H</td>
<td>hydralazine hydrochloride 25 mg tablet, 100</td>
<td>2</td>
<td>2</td>
<td>..</td>
<td>*17.64</td>
<td>18.79</td>
<td>Alphapress 25 AF</td>
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<tr>
<td>1639G</td>
<td>hydralazine hydrochloride 50 mg tablet, 100</td>
<td>2</td>
<td>2</td>
<td>..</td>
<td>*19.36</td>
<td>20.51</td>
<td>Alphapress 50 AF</td>
</tr>
</tbody>
</table>
## Pyrimidine derivatives

**Minoxidil**

*Authority required (STREAMLINED)*

2759

Severe refractory hypertension. Treatment must be initiated by a consultant physician

**Note**

Continuing Therapy Only:

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

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<tbody>
<tr>
<td>2313R</td>
<td>minoxidil 10 mg tablet, 100</td>
<td>1</td>
<td>5</td>
<td>60.61</td>
<td>36.90</td>
<td></td>
<td>Loniten PF</td>
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## Diuretics

### LOW-CEILING DIURETICS, THIAZIDES

**Thiazides, plain**

<table>
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<tr>
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<th>No. of Rpts</th>
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<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>1484D</td>
<td>Hydrochlorothiazide 25 mg tablet, 100</td>
<td>1</td>
<td>1</td>
<td>21.58</td>
<td>22.73</td>
<td></td>
<td>Dithiazide PL</td>
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### LOW-CEILING DIURETICS, EXCL. THIAZIDES

**Sulfonamides, plain**

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<tbody>
<tr>
<td>1585K</td>
<td>Chlorthalidone 25 mg tablet, 50</td>
<td>2</td>
<td>1</td>
<td>*17.92</td>
<td>19.07</td>
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<td>Hygroton 25 LM</td>
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### HIGH-CEILING DIURETICS

**Sulfonamides, plain**

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<tbody>
<tr>
<td>2411X</td>
<td>Frusemide 10 mg/mL oral liquid, 30 mL</td>
<td>¶1</td>
<td>3</td>
<td>25.18</td>
<td>26.33</td>
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<td>Lasix SW</td>
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<table>
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<td>2413B</td>
<td>Frusemide 20 mg/2 mL injection, 5 x 2 mL ampoules</td>
<td>1</td>
<td>..</td>
<td>9.65</td>
<td>10.80</td>
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<tr>
<td>2412Y</td>
<td>Frusemide 40 mg tablet, 100</td>
<td>1</td>
<td>1</td>
<td>8.36</td>
<td>9.51</td>
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<td>APO-Frusemide TX</td>
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CARDIOVASCULAR SYSTEM

<table>
<thead>
<tr>
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<th>Brand Name and Manufacturer</th>
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<td>3</td>
<td>..</td>
<td>15.07</td>
<td>16.22</td>
<td>Urex-Forte FM</td>
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</tbody>
</table>

**FRUSEMIDE**

**Note**

For item codes 2414C and 1810G, pharmaceutical benefits that have the form tablet 20 mg are equivalent for the purposes of substitution.

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
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<td>1</td>
<td>..</td>
<td>8.52</td>
<td>9.67</td>
<td>APO-Frusemide TX</td>
</tr>
<tr>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>Chem mart Frusemide CH</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>Frusemide AN EA</td>
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<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td>Frusid GN</td>
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<td></td>
<td></td>
<td></td>
<td>GenRx Frusemide GX</td>
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<td>Terry White Chemists Frusemide</td>
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<tr>
<td>1810G</td>
<td>frusemide 20 mg tablet, 50</td>
<td>2</td>
<td>1</td>
<td>..</td>
<td>*8.50</td>
<td>9.65</td>
<td>Urex-M FM</td>
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</table>

**Aryloxyacetic acid derivatives**

**ETHACRYNIC ACID**

**Restricted benefit**

Patients hypersensitive to other oral diuretics

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
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<td>8748K</td>
<td>ethacrynic acid 25 mg tablet, 100</td>
<td>2</td>
<td>1</td>
<td>..</td>
<td>*197.64</td>
<td>36.90</td>
<td>Edecrin FK</td>
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</tbody>
</table>

**POTASSIUM-SPARING AGENTS**

**Aldosterone antagonists**

**EPLERENONE**

**Authority required (STREAMLINED)**

2637

Heart failure with a left ventricular ejection fraction of 40% or less occurring within 3 to 14 days following an acute myocardial infarction. Treatment with eplerenone must be commenced within 14 days of an acute myocardial infarction.

The date of the acute myocardial infarction and the date of initiation of eplerenone treatment must be documented in the patient's medical records when PBS-subsidised treatment is initiated

**Caution**

Serum electrolytes should be checked regularly.

**Note**

Continuing Therapy Only:

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

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<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>8879H</td>
<td>eplerenone 25 mg tablet, 30</td>
<td>1</td>
<td>5</td>
<td>..</td>
<td>113.11</td>
<td>36.90</td>
<td>Inspra PF</td>
</tr>
<tr>
<td>8880J</td>
<td>eplerenone 50 mg tablet, 30</td>
<td>1</td>
<td>5</td>
<td>..</td>
<td>113.11</td>
<td>36.90</td>
<td>Inspra PF</td>
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</table>

**SPIRONOLACTONE**

**Caution**

Serum electrolytes should be checked regularly.

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<tbody>
<tr>
<td>2340E</td>
<td>spironolactone 100 mg tablet, 100</td>
<td>1</td>
<td>5</td>
<td>..</td>
<td>29.46</td>
<td>30.61</td>
<td>Spiractin 100 AF</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Aldactone PF</td>
</tr>
<tr>
<td>2339D</td>
<td>spironolactone 25 mg tablet, 100</td>
<td>1</td>
<td>5</td>
<td>..</td>
<td>12.53</td>
<td>13.68</td>
<td>Spiractin 25 AF</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Aldactone PF</td>
</tr>
</tbody>
</table>

**DIURETICS AND POTASSIUM-SPARING AGENTS IN COMBINATION**

**Low-ceiling diuretics and potassium-sparing agents**

**HYDROCHLOROTHIAZIDE + AMILORIDE**

**Caution**

Serum electrolytes should be checked regularly.

<table>
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<tr>
<th>Code</th>
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<tbody>
<tr>
<td>1486F</td>
<td>hydrochlorothiazide 50 mg + amiloride</td>
<td>2</td>
<td>1</td>
<td>..</td>
<td>*13.84</td>
<td>14.99</td>
<td>Moduretic AS</td>
</tr>
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### CARDIOVASCULAR SYSTEM

#### HYDROCHLOROTHIAZIDE + TRIAMTERENE

**Caution**
Serum electrolytes should be checked regularly.

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</thead>
<tbody>
<tr>
<td>1280J</td>
<td>hydrochlorothiazide 25 mg + triamterene 50 mg tablet, 100</td>
<td>1</td>
<td>1</td>
<td></td>
<td>13.23</td>
<td>14.38</td>
<td>Hydrene 25/50</td>
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#### PERIPHERAL VASODILATORS

**Other peripheral vasodilators**

**PHENOXYBENZAMINE**

- **Restricted benefit**
  - Phaeochromocytoma
- **Restricted benefit**
  - Neurogenic urinary retention

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

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<td>1862B</td>
<td>phenoxybenzamine hydrochloride 10 mg capsule, 100</td>
<td>1</td>
<td>5</td>
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<td>67.71</td>
<td>36.90</td>
<td>Dibenzyline</td>
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<tr>
<td>9286R</td>
<td>phenoxybenzamine hydrochloride 10 mg capsule, 100</td>
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<td>5</td>
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<td>1144.81</td>
<td>36.90</td>
<td>Dibenzyline</td>
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<tr>
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<td>phenoxybenzamine hydrochloride 10 mg capsule, 30</td>
<td>3</td>
<td>5</td>
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<td>205.24</td>
<td>36.90</td>
<td>Dibenzyline</td>
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#### BETA BLOCKING AGENTS

**Beta blocking agents, non-selective**

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<tbody>
<tr>
<td>2961W</td>
<td>oxprenolol hydrochloride 40 mg tablet, 100</td>
<td>1</td>
<td>5</td>
<td></td>
<td>48.58</td>
<td>36.90</td>
<td>Corbeton 40</td>
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<tr>
<td>3065H</td>
<td>pindolol 15 mg tablet, 50</td>
<td>1</td>
<td>5</td>
<td></td>
<td>16.26</td>
<td>17.41</td>
<td>Visken 15</td>
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<tr>
<td>3062E</td>
<td>pindolol 5 mg tablet, 100</td>
<td>1</td>
<td>5</td>
<td></td>
<td>30.77</td>
<td>31.92</td>
<td>Barbloc 5</td>
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<td>2565B</td>
<td>propranolol hydrochloride 10 mg tablet, 100</td>
<td>1</td>
<td>5</td>
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<td>10.53</td>
<td>11.68</td>
<td>Deralin 10</td>
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<td>2899N</td>
<td>propranolol hydrochloride 160 mg tablet, 50</td>
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<td>5</td>
<td></td>
<td>14.28</td>
<td>11.68</td>
<td>Inderal</td>
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<td>2566C</td>
<td>propranolol hydrochloride 40 mg tablet, 100</td>
<td>1</td>
<td>5</td>
<td></td>
<td>14.65</td>
<td>12.05</td>
<td>Deralin 40</td>
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**Beta blocking agents, selective**

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<td>1081X</td>
<td>atenolol 50 mg tablet, 30</td>
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<td>8.39</td>
<td>9.54</td>
<td>APO-Atenolol</td>
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|      |                                                      |       |         |             |                                |                                  |                                |
|      |                                                      |       |         |             |                                |                                  |                                |
|      |                                                      |       |         |             |                                |                                  |                                |
## CARDIOVASCULAR SYSTEM

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</tbody>
</table>

### ATENOLOL
**Restricted benefit**
For a patient who is unable to take a solid dose form of atenolol.

2243C
atenolol 50 mg/10 mL oral liquid, 300 mL

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
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</tbody>
</table>

### BISOPROLOL
**Authority required (STREAMLINED)**

3234
Moderate to severe heart failure in a patient stabilised on conventional therapy which must include an ACE inhibitor or Angiotensin II antagonist, if tolerated

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

8606Y
bisoprolol fumarate 10 mg tablet, 28

<table>
<thead>
<tr>
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### METOPROLOL SUCCINATE
**Authority required (STREAMLINED)**

3234
Moderate to severe heart failure in a patient stabilised on conventional therapy which must include an ACE inhibitor or Angiotensin II antagonist, if tolerated
# CARDIOVASCULAR SYSTEM

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### NEBIVOLOL

**Authority required (STREAMLINED)**

3234

Moderate to severe heart failure in a patient stabilised on conventional therapy which must include an ACE inhibitor or Angiotensin II antagonist, if tolerated

**Note**

Continuing Therapy Only:

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

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**Alpha and beta blocking agents**
### CARDIOVASCULAR SYSTEM

**CARVEDILOL**

**Authority required (STREAMLINED)**

- Code 3234
- Note
  - Moderate to severe heart failure in a patient stabilised on conventional therapy which must include an ACE inhibitor or Angiotensin II antagonist, if tolerated

- Code 1735
- Note
  - Patients receiving this drug as a pharmaceutical benefit prior to 1 August 2002

**Note**

Continuing Therapy Only:

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### CARDIOVASCULAR SYSTEM

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### CALCIUM CHANNEL BLOCKERS

#### SELECTIVE CALCIUM CHANNEL BLOCKERS WITH MAINLY VASCULAR EFFECTS

**Dihydropyridine derivatives**

#### AMLODIPINE

**Note**

Pharmaceutical benefits that have the form amlodipine tablet 10 mg (as besylate) and pharmaceutical benefits that have the form amlodipine tablet 10 mg (as maleate) are equivalent for the purposes of substitution.

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#### AMLODIPINE

**Note**

Pharmaceutical benefits that have the form amlodipine tablet 5 mg (as besylate) and pharmaceutical benefits that have the form amlodipine tablet 5 mg (as maleate) are equivalent for the purposes of substitution.

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**SELECTIVE CALCIUM CHANNEL BLOCKERS WITH DIRECT CARDIAC EFFECTS**

**Phenylalkylamine derivatives**

**VERAPAMIL**

**Caution**
The myocardial depressant effects of this drug and of beta-blocking drugs are additive.

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**Benzothiazepine derivatives**

**DILTIAZEM**

**Caution**
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**AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM**

**ACE INHIBITORS, PLAIN**

**ACE inhibitors, plain**

**CAPTOPRIL**

**Caution**
Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

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<th>Premium $</th>
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## CARDIOVASCULAR SYSTEM

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### CAPTOPRIL

**Restricted benefit**

For patients unable to take a solid dose form of an ACE inhibitor

### Caution

Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

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### ENALAPRIL

**Caution**

Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

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### CARDIOVASCULAR SYSTEM

#### FOSINOPRIL

Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

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#### LISINOPRIL

Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

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### PERINDOPRIL

**Caution**

Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

**Note**

Pharmaceutical benefits that have the form perindopril erbumine tablet 8 mg and pharmaceutical benefits that have the form perindopril arginine tablet 10 mg are equivalent for the purposes of substitution.

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### PERINDOPRIL

**Caution**

Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

**Note**

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### PERINDOPRIL

**Caution**

Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

**Note**

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## QUINAPRIL

**Caution**
Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

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## RAMIPRIL

**Caution**
Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

**Note**
Pharmaceutical benefits that have the form ramipril tablet 1.25 mg and pharmaceutical benefits that have the form ramipril capsule 1.25 mg are equivalent for the purposes of substitution.

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## RAMIPRIL

**Caution**
Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

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**RAMIPRIL**

**Caution**

Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

**Note**

Pharmaceutical benefits that have the form ramipril tablet 2.5 mg and pharmaceutical benefits that have the form ramipril capsule 2.5 mg are equivalent for the purposes of substitution.
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**Caution**
Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

**Note**
Pharmaceutical benefits that have the form ramipril tablet 5 mg and pharmaceutical benefits that have the form ramipril capsule 5 mg are equivalent for the purposes of substitution.

**TRANDOLAPRIL**

**Caution**
Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

**ACE INHIBITORS, COMBINATIONS**

**ACE inhibitors and diuretics**

**ENALAPRIL + HYDROCHLOROTHIAZIDE**

**Restricted benefit**
Hypertension

**Clinical criteria:**
The treatment must not be for the initiation of anti-hypertensive therapy,
### CARDIOVASCULAR SYSTEM

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QUINAPRIL + HYDROCHLOROTHIAZIDE

Restricted benefit

Hypertension

Clinical criteria:
The treatment must not be for the initiation of anti-hypertensive therapy, AND
The condition must be inadequately controlled with an ACE inhibitor; OR
The condition must be inadequately controlled with a thiazide diuretic.

Caution
Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

ACE inhibitors and calcium channel blockers

LERCANIDIPINE + ENALAPRIL

Restricted benefit

Hypertension

Clinical criteria:
The treatment must not be for the initiation of anti-hypertensive therapy, AND
The condition must be inadequately controlled with an ACE inhibitor; OR
The condition must be inadequately controlled with a dihydropyridine calcium channel blocker.

Caution
Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

PERINDOPRIL + AMLODIPINE

Restricted benefit

Hypertension

Clinical criteria:
The treatment must not be for the initiation of anti-hypertensive therapy, AND
The condition must be inadequately controlled with an ACE inhibitor; OR
The condition must be inadequately controlled with a dihydropyridine calcium channel blocker.
Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

### RAMIPRIL + FELODIPINE

**Restricted benefit**

**Hypertension**

- Clinical criteria:
  - The treatment must not be for the initiation of anti-hypertensive therapy,
  - AND
  - The condition must be inadequately controlled with an ACE inhibitor; OR
  - The condition must be inadequately controlled with a dihydropyridine calcium channel blocker.

**Caution**

Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

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### TRANDOLAPRIL + VERAPAMIL

**Restricted benefit**

**Hypertension**

- Clinical criteria:
  - The treatment must not be for the initiation of anti-hypertensive therapy,
  - AND
  - The condition must be inadequately controlled with an ACE inhibitor; OR
  - The condition must be inadequately controlled with verapamil.

**Caution**

Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

- **Caution**
  - The myocardial depressant effects of verapamil hydrochloride and of beta-blocking drugs are additive.

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### ANGIOTENSIN II ANTAGONISTS, PLAIN

**Angiotensin II antagonists, plain**

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ANGIOTENSIN II ANTAGONISTS, COMBINATIONS

Angiotensin II antagonists and diuretics

Candesartan + Hydrochlorothiazide

Restricted benefit

Hypertension

Clinical criteria:

The treatment must not be for the initiation of anti-hypertensive therapy,

AND

The condition must be inadequately controlled with an angiotensin II antagonist; OR

The condition must be inadequately controlled with a thiazide diuretic.

Angiotensin II antagonists and diuretics

Candesartan Cilexetil 16 mg + hydrochlorothiazide 12.5 mg tablet, 30

No applications for increased maximum quantities and/or repeats will be authorised for the 320 mg tablet.

Candesartan Cilexetil 32 mg + hydrochlorothiazide 12.5 mg tablet, 30
### Cardiovacular System

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**Eprosartan + Hydrochlorothiazide**

**Restricted Benefit**

**Clinical Criteria:**

- The treatment must not be for the initiation of hypotensive therapy,
- The condition must be inadequately controlled with an Angiotensin II antagonist; OR
- The condition must be inadequately controlled with a thiazide diuretic.

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**Irbesartan + Hydrochlorothiazide**

**Restricted Benefit**

**Clinical Criteria:**

- The treatment must not be for the initiation of hypotensive therapy,
- The condition must be inadequately controlled with an Angiotensin II antagonist; OR
- The condition must be inadequately controlled with a thiazide diuretic.

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**OLMESARTAN MEdoxOMIL + HYDROCHLOROTHIAZIDE**

**Restricted benefit**

**Hypertension**

**Clinical criteria:**

The treatment must not be for the initiation of anti-hypertensive therapy, AND

The condition must be inadequately controlled with an angiotensin II antagonist; OR

The condition must be inadequately controlled with a thiazide diuretic.
## Cardiac System

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### Telmisartan + Hydrochlorothiazide

**Restricted benefit**

**Hypertension**

**Clinical criteria:**

The treatment must not be for the initiation of anti-hypertensive therapy, and

The condition must be inadequately controlled with an angiotensin II antagonist; OR

The condition must be inadequately controlled with a thiazide diuretic.

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
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<th>Dispensed Price for Max. Qty $</th>
<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
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<td>Chem mart Telmisartan HCTZ 40/12.5 CH</td>
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<td>Pritor Plus 40/12.5 mg FI</td>
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<td>Telmisartan HCT Sandoz SZ</td>
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<td>Micardis Plus 80/12.5 mg BY</td>
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</tr>
</tbody>
</table>
### Valsartan + Hydrochlorothiazide

**Restricted benefit**

#### Hypertension

**Clinical criteria:**

The treatment must not be for the initiation of anti-hypertensive therapy, AND

The condition must be inadequately controlled with an angiotensin II antagonist; OR

The condition must be inadequately controlled with a thiazide diuretic.

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
<th>Dispensed Price for Max. Qty</th>
<th>Maximum Recordable Value for Safety Net</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>9373H</td>
<td>valsartan 160 mg + hydrochlorothiazide 12.5 mg tablet, 28</td>
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<td>21.99</td>
<td>23.14</td>
<td>Co-Diovan 160/12.5 NV</td>
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<tr>
<td>9374J</td>
<td>valsartan 160 mg + hydrochlorothiazide 25 mg tablet, 28</td>
<td>1 5 ..</td>
<td>24.06</td>
<td>25.21</td>
<td>Co-Diovan 160/25 NV</td>
<td></td>
</tr>
<tr>
<td>9372G</td>
<td>valsartan 80 mg + hydrochlorothiazide 12.5 mg tablet, 28</td>
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<td>19.08</td>
<td>20.23</td>
<td>Co-Diovan 80/12.5 NV</td>
<td></td>
</tr>
</tbody>
</table>

**Note**

No applications for increased maximum quantities and/or repeats will be authorised for the tablets containing 320 mg valsartan.

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
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<th>Dispensed Price for Max. Qty</th>
<th>Maximum Recordable Value for Safety Net</th>
<th>Brand Name and Manufacturer</th>
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<td>27.77</td>
<td>28.92</td>
<td>Co-Diovan 320/25 NV</td>
<td></td>
</tr>
</tbody>
</table>

### Angiotensin II antagonists and calcium channel blockers

**AMLODIPINE + VALSARTAN**

**Restricted benefit**

#### Hypertension

**Clinical criteria:**

The treatment must not be for the initiation of anti-hypertensive therapy, AND

The condition must be inadequately controlled with an angiotensin II antagonist; OR

The condition must be inadequately controlled with a dihydropyridine calcium channel blocker.

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
<th>Dispensed Price for Max. Qty</th>
<th>Maximum Recordable Value for Safety Net</th>
<th>Brand Name and Manufacturer</th>
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<tr>
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<td>5460J</td>
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<td>32.81</td>
<td>33.96</td>
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### Olmesartan Medoxomil + Amlodipine

**Restricted benefit**

#### Hypertension

**Clinical criteria:**

The treatment must not be for the initiation of anti-hypertensive therapy,

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
<th>Dispensed Price for Max. Qty</th>
<th>Maximum Recordable Value for Safety Net</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>9373H</td>
<td>valsartan 160 mg + hydrochlorothiazide 12.5 mg tablet, 28</td>
<td>1 5 ..</td>
<td>21.99</td>
<td>23.14</td>
<td>Co-Diovan 160/12.5 NV</td>
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<tr>
<td>9374J</td>
<td>valsartan 160 mg + hydrochlorothiazide 25 mg tablet, 28</td>
<td>1 5 ..</td>
<td>24.06</td>
<td>25.21</td>
<td>Co-Diovan 160/25 NV</td>
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<tr>
<td>9372G</td>
<td>valsartan 80 mg + hydrochlorothiazide 12.5 mg tablet, 28</td>
<td>1 5 ..</td>
<td>19.08</td>
<td>20.23</td>
<td>Co-Diovan 80/12.5 NV</td>
<td></td>
</tr>
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</table>

**Note**

No applications for increased maximum quantities and/or repeats will be authorised for the tablets containing 320 mg valsartan.

<table>
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<th>Code</th>
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<th>Maximum Recordable Value for Safety Net</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>9481B</td>
<td>valsartan 320 mg + hydrochlorothiazide 12.5 mg tablet, 28</td>
<td>1 5 ..</td>
<td>25.69</td>
<td>26.84</td>
<td>Co-Diovan 320/12.5 NV</td>
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<tr>
<td>9482C</td>
<td>valsartan 320 mg + hydrochlorothiazide 25 mg tablet, 28</td>
<td>1 5 ..</td>
<td>27.77</td>
<td>28.92</td>
<td>Co-Diovan 320/25 NV</td>
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### Olmesartan Medoxomil + Amlodipine

**Restricted benefit**

#### Hypertension

**Clinical criteria:**

The treatment must not be for the initiation of anti-hypertensive therapy,
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<td>19.18</td>
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<td>MK</td>
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<td>MK</td>
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**TELMISARTAN + AMLODIPINE**

**Restricted benefit**

**Hypertension**

**Clinical criteria:**

The treatment must not be for the initiation of anti-hypertensive therapy,

**AND**

The condition must be inadequately controlled with an angiotensin II antagonist; OR

The condition must be inadequately controlled with a dihydropyridine calcium channel blocker.

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>Dispensed Price for Max. Qty $</th>
<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
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<td>Pritor/Amlodipine</td>
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<td>Pritor/Amlodipine</td>
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</table>

**Angiotensin II antagonists, other combinations**

**AMLODIPINE + VALSARTAN + HYDROCHLOROTHIAZIDE**

**Restricted benefit**

**Hypertension**

**Clinical criteria:**

The treatment must not be for the initiation of anti-hypertensive therapy,

**AND**

The condition must be inadequately controlled with an angiotensin II antagonist; OR

The condition must be inadequately controlled with a dihydropyridine calcium channel blocker.

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>Dispensed Price for Max. Qty $</th>
<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
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<td>..</td>
<td>30.71</td>
<td>31.86</td>
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<td>NV</td>
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<td>NV</td>
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<td>NV</td>
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<td>27.17</td>
<td>28.32</td>
<td>Exforge HCT 5/160/12.5</td>
<td>NV</td>
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<td>28.92</td>
<td>30.07</td>
<td>Exforge HCT 5/160/25</td>
<td>NV</td>
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</table>

**OLMESARTAN + AMLODIPINE + HYDROCHLOROTHIAZIDE**

**Restricted benefit**

**Hypertension**

**Clinical criteria:**

The treatment must not be for the initiation of anti-hypertensive therapy,

**AND**
<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
<th>Premium $</th>
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<td>34.34</td>
<td>35.49</td>
</tr>
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<td>..</td>
<td>30.55</td>
<td>31.70</td>
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<td>5</td>
<td>..</td>
<td>32.77</td>
<td>33.92</td>
</tr>
</tbody>
</table>

The condition must be inadequately controlled with concomitant treatment with two of the following: an angiotensin II antagonist, a dihydropyridine calcium channel blocker or a thiazide diuretic.
GENERAL STATEMENT FOR LIPID-LOWERING DRUGS PRESCRIBED AS PHARMACEUTICAL BENEFITS

Use the following criteria to determine patient eligibility for subsidisation under the PBS for the following drugs:

- atorvastatin calcium
- fluvastatin sodium
- pravastatin sodium
- rosuvastatin calcium
- simvastatin
- fenofibrate
- gemfibrozil

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

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

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

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

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

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

### PATIENT CATEGORY

#### LIPID LEVELS FOR PBS SUBSIDY

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<th>Patients with diabetes mellitus not otherwise included</th>
<th>total cholesterol &gt; 5.5 mmol/L</th>
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<td>Aboriginal or Torres Strait Islander patients</td>
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<td>Patients with hypertension</td>
<td>or total cholesterol &gt; 5.5 mmol/L and HDL cholesterol &lt; 1 mmol/L</td>
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<td>Patients with HDL cholesterol &lt; 1 mmol/L</td>
<td>total cholesterol &gt; 6.5 mmol/L</td>
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<td>Patients with familial hypercholesterolaemia identified by:</td>
<td>If aged 18 years or less at treatment initiation: LDL cholesterol &gt; 4 mmol/L</td>
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<td>DNA mutation; or</td>
<td>If aged more than 18 years at treatment initiation: LDL cholesterol &gt; 5 mmol/L</td>
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<td>tendon xanthomas in the patient or their first or second degree relatives</td>
<td>or total cholesterol &gt; 6.5 mmol/L</td>
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<td>family history of coronary heart disease which has become symptomatic before the age of 60 years in one or more first degree relatives; or</td>
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<td>men aged 35 to 75 years</td>
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<td>post-menopausal women aged up to 75 years</td>
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<td>or triglyceride &gt; 8 mmol/L</td>
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### LIPID MODIFYING AGENTS

#### LIPID MODIFYING AGENTS, PLAIN

**HMG CoA reductase inhibitors**

**ATORVASTATIN**

*Restricted benefit*

For use in patients that meet the criteria set out in the General Statement for Lipid-Lowering Drugs

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### ATORVASTATIN

**Restricted benefit**

For use in patients who meet the criteria set out in the General Statement for Lipid-Lowering Drugs, and who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.

**Note**

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

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### FLUVASTATIN

**Restricted benefit**

For use in patients that meet the criteria set out in the General Statement for Lipid-Lowering Drugs

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**PRAVASTATIN**

**Restricted benefit**

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**Note**

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### Rosuvastatin

**Restricted benefit**

For use in patients who meet the criteria set out in the General Statement for Lipid-Lowering Drugs

#### Clinical criteria:

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

**Note**

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

**Note**

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

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### Rosuvastatin

**Restricted benefit**

For use in patients who meet the criteria set out in the General Statement for Lipid-Lowering Drugs
## CARDIOVASCULAR SYSTEM

### ROSUVASTATIN

**Restricted benefit**

For use in patients who meet the criteria set out in the General Statement for Lipid-Lowering Drugs

**Clinical criteria:**

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

**AND**

The treatment must not be prescribed for hypercholesterolaemia if the patient has heterozygous familial hypercholesterolaemia.

**Note**

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

**Note**

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

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

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

*Restricted benefit*

For use in patients who meet the criteria set out in the General Statement for Lipid-Lowering Drugs

**Clinical criteria:**

The treatment must not be prescribed for hypercholesterolaemia if the patient has heterozygous familial hypercholesterolaemia.
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**Clinical criteria:**

The treatment must not be prescribed for hypercholesterolaemia if the patient has heterozygous familial hypercholesterolaemia.
## SIMVASTATIN

**Restricted benefit**

For use in patients that meet the criteria set out in the General Statement for Lipid-Lowering Drugs

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</table>

**SIMVASTATIN**

**Restricted benefit**

For use in patients who meet the criteria set out in the General Statement for Lipid-Lowering Drugs, and who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements

**Note**

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

**FENOFIBRATE**

**Restricted benefit**

For use in patients that meet the criteria set out in the General Statement for Lipid-Lowering Drugs

**Note**

The risk of serious muscle toxicity is increased if fenofibrate is used concomitantly with HMG CoA reductase inhibitors or other fibrates. Such combination therapy should be used with caution in patients with severe combined dyslipidaemia and high cardiovascular risk without any history of muscular disease and patients monitored closely for chronic signs of muscle toxicity.

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Pack)</th>
<th>No. of Rpts</th>
<th>Premium $ Dispensed Price for Max. Qty $</th>
<th>Maximum Recordable Value for Safety Net $</th>
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</tbody>
</table>

**Fibrates**

**FENOFIBRATE**

**Restricted benefit**

For use in patients that meet the criteria set out in the General Statement for Lipid-Lowering Drugs

**Note**

The risk of serious muscle toxicity is increased if fenofibrate is used concomitantly with HMG CoA reductase inhibitors or other fibrates. Such combination therapy should be used with caution in patients with severe combined dyslipidaemia and high cardiovascular risk without any history of muscular disease and patients monitored closely for chronic signs of muscle toxicity.

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<thead>
<tr>
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<th>No. of Rpts</th>
<th>Premium $ Dispensed Price for Max. Qty $</th>
<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
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FENOFOBATE

Restricted benefit

For use in patients who meet the criteria set out in the General Statement for Lipid-Lowering Drugs, and who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.

Note
The risk of serious muscle toxicity is increased if fenofibrate is used concomitantly with HMG CoA reductase inhibitors or other fibrates. Such combination therapy should be used with caution in patients with severe combined dyslipidaemia and high cardiovascular risk without any history of muscular disease and patients monitored closely for chronic signs of muscle toxicity.

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

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
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<th>No. of Rpts</th>
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GEMFIBROZIL

Restricted benefit

For use in patients that meet the criteria set out in the General Statement for Lipid-Lowering Drugs.

Note
The risk of serious muscle toxicity is increased if gemfibrozil is used concomitantly with HMG CoA reductase inhibitors or other fibrates. Such combination therapy should be used with caution in patients with severe combined dyslipidaemia and high cardiovascular risk without any history of muscular disease and patients monitored closely for chronic signs of muscle toxicity.

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

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<tr>
<th>Code</th>
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<th>Max. Qty (Packs)</th>
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Bile acid sequestrants

CHOLESTYRAMINE

Restricted benefit

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<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
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Treatment, in conjunction with dietary therapy and exercise, for co-administration with an HMG CoA reductase inhibitor (statin) in patients whose cholesterol levels are inadequately controlled with a statin and who have coronary heart disease. Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient’s medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient’s medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

Authority required (STREAMLINED)
3724
Treatment, in conjunction with dietary therapy and exercise, for co-administration with an HMG CoA reductase inhibitor (statin) in patients whose cholesterol levels are inadequately controlled with a statin and who have diabetes mellitus. Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient’s medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient’s medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

Authority required (STREAMLINED)
3725
Treatment, in conjunction with dietary therapy and exercise, for co-administration with an HMG CoA reductase inhibitor (statin) in patients whose cholesterol levels are inadequately controlled with a statin and who have peripheral vascular disease. Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient’s medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

Authority required (STREAMLINED)
3726
Treatment, in conjunction with dietary therapy and exercise, for co-administration with an HMG CoA reductase inhibitor (statin) in patients whose cholesterol levels are inadequately controlled with a statin and who have peripheral vascular disease. Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient’s medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

Authority required (STREAMLINED)
A cholesterol level which shows inadequate control must be documented in the patient’s medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

3727
Treatment, in conjunction with dietary therapy and exercise, for co-administration with an HMG CoA reductase inhibitor (statin) in patients whose cholesterol levels are inadequately controlled with a statin and who have heterozygous familial hypercholesterolaemia. Inadequate control with a statin is defined as follows:

- (1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient’s medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

- (2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient’s medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

3728
Treatment, in conjunction with dietary therapy and exercise, for co-administration with an HMG CoA reductase inhibitor (statin) in patients whose cholesterol levels are inadequately controlled with a statin and who have symptomatic cerebrovascular disease. Inadequate control with a statin is defined as follows:

- (1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient’s medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

- (2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient’s medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

3729
Treatment, in conjunction with dietary therapy and exercise, for co-administration with an HMG CoA reductase inhibitor (statin) in patients whose cholesterol levels are inadequately controlled with a statin and who have family history of coronary heart disease. Inadequate control with a statin is defined as follows:

- (1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient’s medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

- (2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient’s medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

3730
Treatment, in conjunction with dietary therapy and exercise, for co-administration with an HMG CoA reductase inhibitor (statin) in patients whose cholesterol levels are inadequately controlled with a statin and who have hypertension. Inadequate control with a statin is defined as follows:

- (1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient’s medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

- (2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

1989
Patients eligible for PBS-subsidised lipid-lowering medication (according to the criteria set out in the General Statement for Lipid-Lowering Drugs)
CARDIOVASCULAR SYSTEM

LIPID MODIFYING AGENTS, COMBINATIONS

ATORVASTATIN (&) EZETIMIBE

Authority required (STREAMLINED)

Hypercholesterolaemia

Clinical criteria:
The treatment must be in conjunction with dietary therapy and exercise,
AND
Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin),
AND
Patient must have coronary heart disease.

Inadequate control with a statin is defined as follows:

1. The patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e., a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

2. The patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e., a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

Authority required (STREAMLINED)

Hypercholesterolaemia

Clinical criteria:
The treatment must be in conjunction with dietary therapy and exercise,

AND
Patient must have diabetes mellitus.

Inadequate control with a statin is defined as follows:
(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient’s medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient’s medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

Hypercholesterolaemia

**Clinical criteria:**

The treatment must be in conjunction with dietary therapy and exercise,

**AND**

Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin),

**AND**

Patient must have peripheral vascular disease.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient’s medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient’s medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

Hypercholesterolaemia

**Clinical criteria:**

The treatment must be in conjunction with dietary therapy and exercise,

**AND**

Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin),

**AND**

Patient must have heterozygous familial hypercholesterolaemia.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient’s medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient’s medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.
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Authority required (STREAMLINED)

4120
Hypercholesterolaemia

Clinical criteria:
The treatment must be in conjunction with dietary therapy and exercise,

AND

Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin),

AND

Patient must have a family history of coronary heart disease.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient’s medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

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Authority required (STREAMLINED)

4121
Hypercholesterolaemia

Clinical criteria:
The treatment must be in conjunction with dietary therapy and exercise,

AND

Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin),

AND

Patient must have hypertension.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient’s medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

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Authority required (STREAMLINED)

4097
Hypercholesterolaemia

Clinical criteria:
Patient must have homozygous familial hypercholesterolaemia,

AND

Patient must be eligible for PBS-subsidised lipid-lowering medication (according to the criteria set out in the General Statement for Lipid-Lowering
### CARDIOVASCULAR SYSTEM

**Hypercholesterolaemia**

**Clinical criteria:**

Patient must be eligible for PBS-subsidised lipid-lowering medication (according to the criteria set out in the General Statement for Lipid-Lowering Drugs),

**AND**

Patient must have developed a clinically important product-related adverse event during treatment with an HMG CoA reductase inhibitor (statin) necessitating a reduction in the atorvastatin dose.

A clinically important product-related adverse event is defined as follows:

(i) Severe myalgia (muscle symptoms without creatine kinase elevation) which is proven to be temporally associated with statin treatment; or

(ii) Myositis (clinically important creatine kinase elevation, with or without muscle symptoms) demonstrated by results twice the upper limit of normal on a single reading or a rising pattern on consecutive measurements and which is unexplained by other causes; or

(iii) Unexplained, persistent elevations of serum transaminases (greater than 3 times the upper limit of normal) during treatment with a statin.

**Note**

Continuing Therapy Only:

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

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**ATORVASTATIN (&) EZETIMIBE**

**Clinical criteria:**

The treatment must be in conjunction with dietary therapy and exercise,

**AND**

Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin),

**AND**

Patient must have coronary heart disease.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient’s medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient’s medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Clinical criteria:**

The treatment must be in conjunction with dietary therapy and exercise,

**AND**

Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin),

**AND**

Patient must have diabetes mellitus.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient’s medical records when ezetimibe is initiated. The cholesterol level which...
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**Authority required (STREAMLINED)**

4086
Hypercholesterolaemia

**Clinical criteria:**

The treatment must be in conjunction with dietary therapy and exercise,

AND

Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin),

AND

Patient must have peripheral vascular disease.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient’s medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

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**Authority required (STREAMLINED)**

4069
Hypercholesterolaemia

**Clinical criteria:**

The treatment must be in conjunction with dietary therapy and exercise,

AND

Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin),

AND

Patient must have heterozygous familial hypercholesterolaemia.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient’s medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient’s medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

4096
Hypercholesterolaemia

**Clinical criteria:**

The treatment must be in conjunction with dietary therapy and exercise,

AND

Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin),

AND

Patient must have symptomatic cerebrovascular disease.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a
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(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

4120

Hypercholesterolaemia

**Clinical criteria:**

The treatment must be in conjunction with dietary therapy and exercise, AND

Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), AND

Patient must have a family history of coronary heart disease.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

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**Authority required (STREAMLINED)**

4121

Hypercholesterolaemia

**Clinical criteria:**

The treatment must be in conjunction with dietary therapy and exercise, AND

Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), AND

Patient must have hypertension.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

4097

Hypercholesterolaemia

**Clinical criteria:**

Patient must have homozygous familial hypercholesterolaemia, AND

Patient must be eligible for PBS-subsidised lipid-lowering medication (according to the criteria set out in the General Statement for Lipid-Lowering Drugs).

**Note**

Continuing Therapy Only:
### EZETIMIBE + SIMVASTATIN

**Authority required (STREAMLINED)**

**4068 Hypercholesterolaemia**

**Clinical criteria:**

The treatment must be in conjunction with dietary therapy and exercise,

AND

Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin),

AND

Patient must have coronary heart disease.

Inadequate control with a statin is defined as follows:

1. where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

2. where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient’s medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

**4085 Hypercholesterolaemia**

**Clinical criteria:**

The treatment must be in conjunction with dietary therapy and exercise,

AND

Patient must have diabetes mellitus.

Inadequate control with a statin is defined as follows:

1. where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient’s medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

2. where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient’s medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

**4086 Hypercholesterolaemia**

**Clinical criteria:**

The treatment must be in conjunction with dietary therapy and exercise,

AND

Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin),

AND

Patient must have peripheral vascular disease.

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**Authority required (STREAMLINED)**

**4069**
Hypercholesterolaemia

**Clinical criteria:**
The treatment must be in conjunction with dietary therapy and exercise,

AND
Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin),

AND
Patient must have heterozygous familial hypercholesterolaemia.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient’s medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

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**Authority required (STREAMLINED)**

**4096**
Hypercholesterolaemia

**Clinical criteria:**
The treatment must be in conjunction with dietary therapy and exercise,

AND
Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin),

AND
Patient must have symptomatic cerebrovascular disease.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient’s medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

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AND

Patient must have a family history of coronary heart disease.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e., a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient’s medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

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**Authority required (STREAMLINED)**

4121
Hypercholesterolaemia

**Clinical criteria:**

The treatment must be in conjunction with dietary therapy and exercise,

AND

Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin),

AND

Patient must have hypertension.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e., a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient’s medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e., a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient’s medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

4097
Hypercholesterolaemia

**Clinical criteria:**

Patient must have homozygous familial hypercholesterolaemia,

AND

Patient must be eligible for PBS-subsidised lipid-lowering medication (according to the criteria set out in the General Statement for Lipid-Lowering Drugs).

**Authority required (STREAMLINED)**

4147
Hypercholesterolaemia

**Clinical criteria:**

Patient must be eligible for PBS-subsidised lipid-lowering medication (according to the criteria set out in the General Statement for Lipid-Lowering Drugs),

AND

Patient must have developed a clinically important product-related adverse event during treatment with an HMG CoA reductase inhibitor (statin) necessitating a reduction in the statin dose.

A clinically important product-related adverse event is defined as follows:

(i) Severe myalgia (muscle symptoms without creatine kinase elevation) which is proven to be temporally associated with statin treatment; or

(ii) Myositis (clinically important creatine kinase elevation, with or without muscle symptoms) demonstrated by results twice the upper limit of normal on a single reading or a rising pattern on consecutive measurements and which is unexplained by other causes; or

(iii) Unexplained, persistent elevations of serum transaminases (greater than 3 times the upper limit of normal) during treatment with a statin.

**Note**

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been
EZETIMIBE + SIMVASTATIN

**Authority required (STREAMLINED)**

**4068**
Hypercholesterolaemia

**Clinical criteria:**
The treatment must be in conjunction with dietary therapy and exercise,

**AND**
Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin),

**AND**
Patient must have coronary heart disease.

Inadequate control with a statin is defined as follows:

1. where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient’s medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

2. where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient’s medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

**4085**
Hypercholesterolaemia

**Clinical criteria:**
The treatment must be in conjunction with dietary therapy and exercise,

**AND**
Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin),

**AND**
Patient must have diabetes mellitus.

Inadequate control with a statin is defined as follows:

1. where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient’s medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated;

2. where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient’s medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

**4086**
Hypercholesterolaemia

**Clinical criteria:**
The treatment must be in conjunction with dietary therapy and exercise,

**AND**
Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin),

**AND**
Patient must have peripheral vascular disease.

Inadequate control with a statin is defined as follows:

1. where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-
maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient’s medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient’s medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

4096
Hypercholesterolaemia

**Clinical criteria:**

The treatment must be in conjunction with dietary therapy and exercise,

AND

Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin),

AND

Patient must have heterozygous familial hypercholesterolaemia.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient’s medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient’s medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

4096
Hypercholesterolaemia

**Clinical criteria:**

The treatment must be in conjunction with dietary therapy and exercise,

AND

Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin),

AND

Patient must have symptomatic cerebrovascular disease.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient’s medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient’s medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

4120
Hypercholesterolaemia

**Clinical criteria:**

The treatment must be in conjunction with dietary therapy and exercise,

AND

Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin),

AND

Patient must have a family history of coronary heart disease.
CARDIOVASCULAR SYSTEM

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient’s medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient’s medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

4221
Hypercholesterolaemia

**Clinical criteria:**
The treatment must be in conjunction with dietary therapy and exercise,

AND
Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin),

AND
Patient must have hypertension.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient’s medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient’s medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

4097
Hypercholesterolaemia

**Clinical criteria:**
Patient must have homozygous familial hypercholesterolaemia,

AND
Patient must be eligible for PBS-subsidised lipid-lowering medication (according to the criteria set out in the General Statement for Lipid-Lowering Drugs).

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

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**HMG CoA reductase inhibitors, other combinations**

**AMLODIPINE + ATORVASTATIN**

**Restricted benefit**
For use in patients who have hypertension and/or angina and who meet the criteria set out in the General Statement for Lipid-Lowering Drugs, and who are currently receiving treatment with a dihydropyridine calcium channel blocker

**Restricted benefit**
For use in patients who have hypertension and/or angina and who meet the criteria set out in the General Statement for Lipid-Lowering Drugs, and whose blood pressure and/or angina is inadequately controlled with other classes of antihypertensive and/or anti-anginal agent, and in whom adjunctive therapy with a dihydropyridine calcium channel blocker would be appropriate

**Restricted benefit**
For use in patients who have hypertension and/or angina and who meet the criteria set out in the General Statement for Lipid-Lowering Drugs, and who are intolerant of the side effects of other classes of antihypertensive and/or anti-anginal agent, and in whom replacement therapy with a dihydropyridine calcium channel blocker would be appropriate
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### DERMATOLOGICALS

#### ANTIFUNGALS FOR DERMATOLOGICAL USE

#### ANTIFUNGALS FOR TOPICAL USE

**Antibiotics**

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**Imidazole and triazole derivatives**

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</tr>
<tr>
<td></td>
<td>miconazole nitrate 2% (20 mg/g) cream, 70 g</td>
<td>‡1</td>
<td>1</td>
<td>..</td>
<td>15.90</td>
<td>17.05</td>
<td>Daktarin JT</td>
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<td>9029F NP</td>
<td>9029F NP</td>
<td>9029F NP</td>
<td>9029F NP</td>
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<tr>
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<td>miconazole nitrate 2% (20 mg/g) powder: dusting, 30 g</td>
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<td>2</td>
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<td>15.90</td>
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<td>Daktarin JT</td>
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**Other antifungals for topical use**

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<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
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<td>9160D NP</td>
<td>9160D NP</td>
<td>9160D NP</td>
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<tr>
<td></td>
<td>terbinafine hydrochloride 1% cream, 15 g</td>
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#### ANTIFUNGALS FOR SYSTEMIC USE

**Antifungals for systemic use**

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<td>1460W NP</td>
<td>1460W NP</td>
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<td>griseofulvin 125 mg tablet, 100</td>
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<td>2</td>
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<td>26.21</td>
<td>27.36</td>
<td>Grisovin QA</td>
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<td>2982Y NP</td>
<td>2982Y NP</td>
<td>2982Y NP</td>
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<td>27.33</td>
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**TERBINAFINE** Authority required

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<td>2285G NP</td>
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<td>terbinafine 250 mg tablet, 42</td>
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<td>..</td>
<td>..</td>
<td>45.58</td>
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### DERMATOLOGICALS

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<tr>
<td></td>
<td>Proximal or extensive (greater than 80% nail involvement) onychomycosis due to dermatophyte infection where topical treatment has failed. This infection must be proven by microscopy or culture and confirmed by an Approved Pathology Authority. The date of the pathology report must be provided at the time of application and must not be more than 12 months old</td>
<td></td>
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<td></td>
<td>Note</td>
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<td>No applications for increased maximum quantities and/or repeats will be authorised.</td>
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<td>GenRx Terbinafine</td>
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<tr>
<td>8864M</td>
<td>coal tar prepared 1% (10 mg/g) lotion, 100 mL</td>
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<td>2</td>
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<td>33.42</td>
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<td></td>
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<td>For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.</td>
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<tr>
<td>2080L</td>
<td>calcipotriol 0.005% cream, 30 g</td>
<td>‡1</td>
<td>1</td>
<td>..</td>
<td>28.40</td>
<td>29.55</td>
<td>Daivonex</td>
</tr>
<tr>
<td>NP</td>
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</tr>
<tr>
<td></td>
<td>CALCIPOTRIOL + BETAMETHASONE DIPROPIONATE</td>
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<td>Chronic stable plaque type psoriasis vulgaris</td>
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<td>Clinical criteria:</td>
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<tr>
<td></td>
<td>The condition must be on the patient’s scalp.</td>
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<tr>
<td></td>
<td>AND</td>
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</tr>
</tbody>
</table>
The condition must be inadequately controlled with either a vitamin D analogue or potent topical corticosteroid as monotherapy, AND Patient must require more than 30 grams of the product per month.

**Note**

Continuing Therapy Only:

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

**10075G**

betamethasone (as dipropionate) 0.05% + calcipotriol 0.005% gel, 60 g

CALCIPOTRIOL + BETAMETHASONE DIPROPIONATE

**Restricted benefit**

Chronic stable plaque type psoriasis vulgaris of the scalp in a patient who is not adequately controlled with either calcipotriol or potent topical corticosteroid monotherapy

**Note**

Continuing Therapy Only:

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**5276Q**

calcipotriol 0.005% + betamethasone (as dipropionate) 0.05% gel, 30 g

CALCIPOTRIOL + BETAMETHASONE DIPROPIONATE

**Restricted benefit**

Chronic stable plaque type psoriasis vulgaris in a patient who is not adequately controlled with either calcipotriol or potent topical corticosteroid monotherapy

**Note**

Continuing Therapy Only:

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

**9494Q**

calcipotriol 0.005% + betamethasone (as dipropionate) 0.05% ointment, 30 g

**ANTIPSORIATICS FOR SYSTEMIC USE**

**Retinoids for treatment of psoriasis**

**ACITRETIN**

**Authority required (STREAMLINED)**

1366

Severe intractable psoriasis

**Authority required (STREAMLINED)**

1363

Severe forms of disorders of keratinisation

**Caution**

This drug is a potent teratogen—pregnancy should be avoided for at least two years after cessation of therapy.

**Note**

Care must be taken to comply with the provisions of State/Territory law when prescribing acitretin.

**2019G**

acitretin 10 mg capsule, 100

2 1 36.90 Acitretin Actavis GN Acitretin Neotigason Novatin IA GN

**2020H**

acitretin 25 mg capsule, 100

2 1 36.90 Acitretin Actavis GN Acitretin Neotigason Novatin IA GN

**SULFONAMIDES**

**SULFADIAZINE SILVER**
### DERMATOLOGICALS

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
<th>Premium $</th>
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<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Restricted benefit</strong></td>
<td>Prevention and treatment of infection in partial or full skin thickness loss due to burns</td>
<td></td>
<td></td>
<td></td>
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<td></td>
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</tr>
<tr>
<td><strong>Restricted benefit</strong></td>
<td>Prevention and treatment of infection in partial or full skin thickness loss due to epidermolysis bullosa</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td><strong>Restricted benefit</strong></td>
<td>Stasis ulcers</td>
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<tr>
<td>9479X NP</td>
<td>sulfadiazine silver 1% (10 mg/g) cream, 50 g</td>
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<td>...</td>
<td>...</td>
<td>19.49</td>
<td>20.64</td>
<td>Flamazine SN</td>
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</table>

### CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS

#### CORTICOSTEROIDS, PLAIN

##### Corticosteroids, weak (group I)

#### HYDROCORTISONE ACETATE

**Restricted benefit**

Treatment of corticosteroid-responsive dermatoses

<table>
<thead>
<tr>
<th>Code</th>
<th>Name</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>Dispensed Price for Max. Qty $</th>
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<th>Brand Name</th>
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<tbody>
<tr>
<td>2887Y NP</td>
<td>hydrocortisone acetate 1% (10 mg/g) cream, 30 g</td>
<td>$\dagger$1</td>
<td>1</td>
<td>...</td>
<td>9.23</td>
<td>10.38</td>
<td>a Cortic-DS 1%</td>
</tr>
<tr>
<td>5111B DP</td>
<td>hydrocortisone acetate 1% (10 mg/g) cream, 30 g</td>
<td>$\dagger$1</td>
<td>...</td>
<td>...</td>
<td>2.69</td>
<td>10.38</td>
<td>a Sigmacort</td>
</tr>
<tr>
<td>2881P NP</td>
<td>hydrocortisone acetate 1% (10 mg/g) cream, 50 g</td>
<td>$\dagger$1</td>
<td>1</td>
<td>...</td>
<td>8.90</td>
<td>10.05</td>
<td>a Cortic-DS 1%</td>
</tr>
<tr>
<td>5113D DP</td>
<td>hydrocortisone acetate 1% (10 mg/g) cream, 50 g</td>
<td>$\dagger$1</td>
<td>...</td>
<td>...</td>
<td>8.90</td>
<td>10.05</td>
<td>a Sigmacort</td>
</tr>
<tr>
<td>2888B NP</td>
<td>hydrocortisone acetate 1% (10 mg/g) ointment, 30 g</td>
<td>$\dagger$1</td>
<td>1</td>
<td>...</td>
<td>9.23</td>
<td>10.38</td>
<td>a Cortic-DS 1%</td>
</tr>
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<td>5112C DP</td>
<td>hydrocortisone acetate 1% (10 mg/g) ointment, 30 g</td>
<td>$\dagger$1</td>
<td>...</td>
<td>...</td>
<td>8.90</td>
<td>10.05</td>
<td>a Sigmacort</td>
</tr>
<tr>
<td>2882Q NP</td>
<td>hydrocortisone acetate 1% (10 mg/g) ointment, 50 g</td>
<td>$\dagger$1</td>
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<td>...</td>
<td>8.90</td>
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<td>a Cortic-DS 1%</td>
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<td>$\dagger$1</td>
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<td>8.90</td>
<td>10.05</td>
<td>a Sigmacort</td>
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</table>

#### CORTICOSTEROIDS, moderately potent (group II)

##### TRIAMCINOLONE

**Restricted benefit**

Treatment of corticosteroid-responsive dermatoses

<table>
<thead>
<tr>
<th>Code</th>
<th>Name</th>
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<th>No. of Rpts</th>
<th>Premium $</th>
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<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name</th>
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<tbody>
<tr>
<td>2117K NP</td>
<td>triamcinolone acetonide 0.02% (200 microgram/g) cream, 100 g</td>
<td>2</td>
<td>...</td>
<td>...</td>
<td>*14.74</td>
<td>15.89</td>
<td>a Tricortone</td>
</tr>
<tr>
<td>2118L NP</td>
<td>triamcinolone acetonide 0.02% (200 microgram/g) ointment, 100 g</td>
<td>2</td>
<td>...</td>
<td>...</td>
<td>*18.52</td>
<td>15.89</td>
<td>a Aristocort 0.02%</td>
</tr>
</tbody>
</table>

#### CORTICOSTEROIDS, potent (group III)

##### BETAMETHASONE DIPROPIONATE

**Restricted benefit**

Treatment of corticosteroid-responsive dermatoses

#### Note

Continuing Therapy Only:

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

<table>
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<tr>
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<td>$\dagger$1</td>
<td>1</td>
<td>...</td>
<td>13.48</td>
<td>14.63</td>
<td>a Eleuphrat</td>
</tr>
<tr>
<td>2118L NP</td>
<td>triamcinolone acetonide 0.02% (200 microgram/g) ointment, 100 g</td>
<td>2</td>
<td>...</td>
<td>...</td>
<td>*18.52</td>
<td>15.89</td>
<td>a Aristocort 0.02%</td>
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<td>24.56</td>
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<td>Betnovate 1/2 QA</td>
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<tr>
<td>2813C</td>
<td>betamethasone (as valerate) 0.05% (500 microgram/g) cream, 15 g</td>
<td>‡1 1</td>
<td>..</td>
<td>8.75</td>
<td>2.94</td>
<td>9.90</td>
<td>Cortival 1/2 FM</td>
</tr>
<tr>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Betnovate 1/2 QA</td>
</tr>
<tr>
<td>8054X</td>
<td>methylprednisolone aceponate 0.1% (1 mg/g) cream, 15 g</td>
<td>‡1 ..</td>
<td>..</td>
<td>14.32</td>
<td>3.07</td>
<td>15.42</td>
<td>Advantan CS</td>
</tr>
<tr>
<td>8055Y</td>
<td>methylprednisolone aceponate 0.1% (1 mg/g) ointment, 15 g</td>
<td>‡1 ..</td>
<td>..</td>
<td>14.32</td>
<td>3.07</td>
<td>15.42</td>
<td>Advantan CS</td>
</tr>
<tr>
<td>8128T</td>
<td>methylprednisolone aceponate 0.1% (1 mg/g) ointment, 15 g</td>
<td>‡1 ..</td>
<td>..</td>
<td>14.32</td>
<td>3.07</td>
<td>15.42</td>
<td>Advantan CS</td>
</tr>
<tr>
<td>8618N</td>
<td>methylprednisolone aceponate 0.1% (1 mg/g) lotion, 20 g</td>
<td>‡1 ..</td>
<td>..</td>
<td>14.99</td>
<td>3.07</td>
<td>16.14</td>
<td>Advantan CS</td>
</tr>
<tr>
<td>1913Q</td>
<td>mometasone furoate 0.1% (1 mg/g) cream, 15 g</td>
<td>‡1 ..</td>
<td>..</td>
<td>12.35</td>
<td>3.07</td>
<td>13.50</td>
<td>Novasone FR</td>
</tr>
<tr>
<td>8043H</td>
<td>mometasone furoate 0.1% lotion, 30 mL</td>
<td>‡1 ..</td>
<td>..</td>
<td>15.58</td>
<td>3.07</td>
<td>16.73</td>
<td>Novasone FR</td>
</tr>
<tr>
<td>1915T</td>
<td>mometasone furoate 0.1% ointment, 15</td>
<td>‡1 ..</td>
<td>..</td>
<td>12.35</td>
<td>3.07</td>
<td>13.50</td>
<td>Novasone FR</td>
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### DERMATOLOGICALS

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<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
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<tr>
<td>NP</td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td>a Zatamil EO</td>
</tr>
<tr>
<td></td>
<td><strong>Corticosteroids, very potent (group IV)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>a Elocon MK</td>
</tr>
<tr>
<td></td>
<td><strong>CLOBETASOL</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>Authority required</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Moderate to severe scalp psoriasis</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>Clinical criteria:</strong></td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>The condition must be inadequately controlled with either a vitamin D analogue or potent topical corticosteroid as monotherapy; OR</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>The condition must be inadequately controlled with combination use of a vitamin D analogue and potent topical corticosteroid.</td>
<td></td>
<td></td>
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</tr>
<tr>
<td></td>
<td><strong>Population criteria:</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Patient must be aged 18 years or older.</td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>10080M</td>
<td>clobetasol propionate 0.05% shampoo, 125 mL</td>
<td>‡1</td>
<td>1</td>
<td>...</td>
<td>48.98</td>
<td>36.90</td>
<td>Clobex GA</td>
</tr>
</tbody>
</table>

### ANTI-ACNE PREPARATIONS

#### ANTI-ACNE PREPARATIONS FOR TOPICAL USE

**Retinoids for topical use in acne**

**ADAPALENE + BENZOYL PEROXIDE**

**Restricted benefit**

Acute treatment, in combination with an oral antibiotic, of severe acne vulgaris

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Pack(s))</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>Dispensed Price for Max. Qty $</th>
<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>8954G</td>
<td>adapalene 0.1% + benzoyl peroxide 2.5% gel, 30 g</td>
<td>‡1</td>
<td>1</td>
<td>...</td>
<td>37.27</td>
<td>36.90</td>
<td>Epiduo GA</td>
</tr>
</tbody>
</table>

**ADAPALENE + BENZOYL PEROXIDE**

**Restricted benefit**

Maintenance treatment of severe acne vulgaris

**Note**

Continuing Therapy Only:

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

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Pack(s))</th>
<th>No. of Rpts</th>
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<th>Dispensed Price for Max. Qty $</th>
<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>895SH</td>
<td>adapalene 0.1% + benzoyl peroxide 2.5% gel, 30 g</td>
<td>‡1</td>
<td>3</td>
<td>...</td>
<td>37.27</td>
<td>36.90</td>
<td>Epiduo GA</td>
</tr>
</tbody>
</table>

#### ANTI-ACNE PREPARATIONS FOR SYSTEMIC USE

**Retinoids for treatment of acne**

**ISOTRETINOIN**

**Authority required [STREAMLINED]**

Severe cystic acne not responsive to other therapy

**Caution**

This drug causes birth defects. Isotretinoin has been reported to cause other frequent and potentially serious toxicity.

**Note**

Care must be taken to comply with the provisions of State/Territory law when prescribing isotretinoin.

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
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<th>No. of Rpts</th>
<th>Premium $</th>
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<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>2591J</td>
<td>isotretinoin 10 mg capsule, 60</td>
<td>1</td>
<td>3</td>
<td>...</td>
<td>52.59</td>
<td>36.90</td>
<td>a APO-Isotretinoin TX</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>a Dermatane ER</td>
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<tr>
<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>a Isotretinoin AN RA</td>
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<td></td>
<td></td>
<td></td>
<td>a Isotretinoin SCP 10 OR</td>
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<td></td>
<td></td>
<td></td>
<td>a Oratane CR</td>
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<tr>
<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>a Roaccutane RO</td>
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<td></td>
<td></td>
<td></td>
<td>a Rocta 10 QA</td>
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<tr>
<td>2592K</td>
<td>isotretinoin 20 mg capsule, 60</td>
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<td>3</td>
<td>...</td>
<td>77.62</td>
<td>36.90</td>
<td>a APO-Isotretinoin TX</td>
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<td></td>
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<td>a Dermatane ER</td>
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<td>a GenRx Isotretinoin GA</td>
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<td></td>
<td></td>
<td>a Isotretinoin AN WX</td>
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<td></td>
<td>a Isotretinoin SCP 20 TX</td>
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**DERMATOLOGICALS**

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<th>Premium $</th>
<th>Dispensed Price for Max. Qty $</th>
<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
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<tr>
<td>2549E</td>
<td>isotretinoin 40 mg capsule, 30</td>
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<td>3</td>
<td>..</td>
<td>70.71</td>
<td>36.90</td>
<td>a Oratane GN a Roaccutane RO a Recta 20 QA a Dermatane ER a Oratane GN</td>
</tr>
</tbody>
</table>

**OTHER DERMATOLOGICAL PREPARATIONS**

**Agents for dermatitis, excluding corticosteroids**

**PIMECROLIMUS**

**Authority required**

Treatment of facial or eyelid atopic dermatitis in patients aged at least 3 months with 1 or more of the following contraindications to topical corticosteroids:

- (i) perioral dermatitis;
- (ii) periorbital dermatitis;
- (iii) rosacea;
- (iv) epidermal atrophy;
- (v) dermal atrophy;
- (vi) allergy to topical corticosteroids;
- (vii) cataracts;
- (viii) glaucoma;
- (ix) raised intraocular pressure

**Authority required**

Short-term (up to 3 weeks) intermittent treatment of atopic dermatitis of the face or eyelids in patients aged at least 3 months who fail to achieve satisfactory disease control with intermittent topical corticosteroid therapy, and where more than 3 months have passed since the initial diagnosis of atopic dermatitis.

Failure to achieve satisfactory disease control with intermittent topical corticosteroid therapy is manifest by:

- (i) failure of the facial skin to clear despite at least 2 weeks of topical hydrocortisone 1% applied every day; or
- (ii) failure of the facial skin to clear despite at least 1 week of a moderate or potent topical corticosteroid applied every day; or
- (iii) clearing of the facial skin with at least 2 weeks of topical hydrocortisone 1% applied every day, but almost immediate and significant flare in facial disease (within 48 hours) upon stopping topical corticosteroids, occurring on at least 2 consecutive occasions; or
- (iv) clearing of the facial skin with at least 1 week of a moderate or potent topical corticosteroid applied every day, but almost immediate and significant flare in facial disease (within 48 hours) upon stopping topical corticosteroids, occurring on at least 2 consecutive occasions

**Note**

No applications for increased maximum quantities and/or repeats will be authorised. Only 1 authority application per 6 months, per patient, will be authorised.

8802G pimecrolimus 1% (10 mg/g) cream, 15 g ¶1 1 .. 34.13 35.28 Elidel HM

**Other dermatologicals**

**DAPSONE**

**Note**

Shared Care Model:

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

1272Y dapsone 100 mg tablet, 100 1 1 .. 114.18 36.90 Link Medical Products Pty Ltd LM

8801F dapsone 25 mg tablet, 100 1 1 .. 100.92 36.90 Link Medical Products Pty Ltd LM

**IMIQUIMOD**

**Authority required**

Superficial basal cell carcinoma

**Clinical criteria:**

The condition must be previously untreated,

AND
The condition must be confirmed by biopsy, AND
Patient must have normal immune function, AND
The condition must not be suitable for treatment with surgical excision; OR
The condition must not be suitable for treatment with cryotherapy; OR
The condition must not be suitable for treatment with curettage with diathermy, AND
Patient must require topical drug therapy.
The date of the pathology report and name of the Approved Pathology Authority must be provided at the time of application.

Note
The patient or carer must be able to understand and administer the imiquimod dosing regimen.

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

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

Note
Treatment of recurrent (previously treated) lesions will not be authorised.

Note
Pharmaceutical benefits that have the form imiquimod single use sachets and pharmaceutical benefits that have the form imiquimod multi-use pump are equivalent for the purposes of substitution.

<table>
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<tr>
<th>Code</th>
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<th>Brand Name and Manufacturer</th>
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<td>2546B</td>
<td>imiquimod 5% cream, 12 x 250 mg sachets</td>
<td>1</td>
<td>1</td>
<td>135.72</td>
<td>36.90</td>
<td>Aldara IA</td>
</tr>
<tr>
<td></td>
<td></td>
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</tr>
<tr>
<td>2637T</td>
<td>imiquimod 5% cream, 2 x 2 g pump packs</td>
<td>1</td>
<td>1</td>
<td>135.72</td>
<td>36.90</td>
<td>Aldara Pump IA</td>
</tr>
<tr>
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</tr>
</tbody>
</table>
GENITO URINARY SYSTEM AND SEX HORMONES

OTHER GYNECOLOGICALS

OXYTOCICS

Prostaglandins

MISOPROSTOL
Authority required
Termination of an intra-uterine pregnancy

Clinical criteria:
The condition must be an intra-uterine pregnancy of up to 49 days of gestation,
AND
The treatment must be in sequential combination with mifepristone 200 mg.

Treatment criteria:
Must be treated by a prescriber who is registered with the MS 2 Step Prescribing Program.

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

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

2672P
misoprostol 200 microgram tablet, 4
1
1
...
8.08
9.23
GyMiso
XH

CONTRACEPTIVES FOR TOPICAL USE

Intrauterine contraceptives

LEVONORGESTREL
Restricted benefit
Contraception

Restricted benefit
Idiopathic menorrhagia where oral treatments are ineffective

Restricted benefit
Idiopathic menorrhagia where oral treatments are contraindicated

8633J
levonorgestrel 52 mg drug delivery system: intrauterine, 1 system
1
...
...
266.56
36.90
Mirena
BN

OTHER GYNECOLOGICALS

Prolactine inhibitors

BROMOCRIPTINE
Restricted benefit
Acromegaly

Restricted benefit
Parkinson's disease

Restricted benefit
Pathological hyperprolactinaemia where surgery is not indicated

Restricted benefit
Pathological hyperprolactinaemia where surgery has already been used with incomplete resolution

Restricted benefit
Pathological hyperprolactinaemia where radiotherapy is not indicated

Restricted benefit
Pathological hyperprolactinaemia where radiotherapy has already been used with incomplete resolution

Note
Care should be taken when treating patients with advanced age and significant cognitive impairment with dopamine agonists.

For item codes 1443Y and 1559C, pharmaceutical benefits that have the form tablet 2.5 mg (base) are equivalent for the purposes of substitution.

1443Y
bromocriptine 2.5 mg tablet, 30
2
5
...
*31.76
32.91
a
Parlodel
NV
### GENITO URINARY SYSTEM AND SEX HORMONES

**Code** | **Name, Restriction, Manner of Administration and Form** | **Max. Qty (Packs)** | **No. of Rpts** | **Premium $** | **Dispensed Price for Max. Qty $** | **Maximum Recordable Value for Safety Net $** | **Brand Name and Manufacturer**
---|---|---|---|---|---|---|---
1559C | bromocriptine 2.5 mg tablet, 60 | 1 | 5 | .. | 31.76 | 32.91 | Kripton 2.5 AF

#### BROMOCRIPTINE

**Restricted benefit**

Prevention of the onset of lactation in the puerperium for medical reasons

1444B | bromocriptine 2.5 mg tablet, 30 | 1 | .. | .. | 19.26 | 20.41 | a Kripton 2.5 AF

#### CABERGOLINE

**Restricted benefit**

Prevention of the onset of lactation in the puerperium for medical reasons

8115D | cabergoline 500 microgram tablet, 2 | 1 | .. | .. | 22.12 | 23.27 | a Dostan GN

#### CABERGOLINE

**Authority required (STREAMLINED)**

2659
Pathological hyperprolactinaemia where surgery is not indicated

**Authority required (STREAMLINED)**

2660
Pathological hyperprolactinaemia where surgery has already been used with incomplete resolution

**Authority required (STREAMLINED)**

2661
Pathological hyperprolactinaemia where radiotherapy is not indicated

**Authority required (STREAMLINED)**

2662
Pathological hyperprolactinaemia where radiotherapy has already been used with incomplete resolution

8114C | cabergoline 500 microgram tablet, 8 | 1 | 5 | .. | 65.57 | 36.90 | a Dostan GN

#### QUINAGOLIDE

**Authority required (STREAMLINED)**

2659
Pathological hyperprolactinaemia where surgery is not indicated

**Authority required (STREAMLINED)**

2660
Pathological hyperprolactinaemia where surgery has already been used with incomplete resolution

**Authority required (STREAMLINED)**

2661
Pathological hyperprolactinaemia where radiotherapy is not indicated

**Authority required (STREAMLINED)**

2662
Pathological hyperprolactinaemia where radiotherapy has already been used with incomplete resolution

8860H | quinagolide 25 microgram tablet [3 tablets] & inert substance tablet [28], 112 | 1 | .. | .. | 11.81 | 12.96 | Norprolac FP

8822H | quinagolide 75 microgram tablet, 30 | 1 | 5 | .. | 55.13 | 36.90 | Norprolac FP

#### SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM

**HORMONAL CONTRACEPTIVES FOR SYSTEMIC USE**

**Progestogens and estrogens, fixed combinations**

1394J | ethinyloestradiol 30 microgram + levonorgestrel 150 microgram tablet [84] & inert substance tablet [28], 112 [4 x 28] | 1 | 2 | .. | 15.64 | 16.79 | b Monofeme 28 FZ

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Note: The table includes information on the names, restrictions, manner of administration, and form of various medications, along with details on maximum quantities, premium and dispensed prices, and brand names and manufacturers.
<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
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<th>Premium $</th>
<th>Dispensed Price for Max. Qty $</th>
<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1456P</td>
<td>ethinylestradiol 50 microgram + levonorgestrel 125 microgram tablet [84] (&amp;) inert substance tablet [28], 112 [4 x 28]</td>
<td>1</td>
<td>2</td>
<td>..</td>
<td>11.37</td>
<td>27.01</td>
<td>a Evelyn 150/30 ED GQ</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>a Femme-Tab ED 30/150 AE</td>
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<td>a Levlen ED SY</td>
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<td></td>
<td></td>
<td></td>
<td>a Micronelle 30 ED TX</td>
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<td></td>
<td></td>
<td></td>
<td>a Nordette 28 PF</td>
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<td></td>
<td></td>
<td></td>
<td>a Microgynon 30 ED BN</td>
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<tr>
<td>2416E</td>
<td>ethinylestradiol 20 microgram + levonorgestrel 100 microgram tablet [84] (&amp;) inert substance tablet [28], 112 [4 x 28]</td>
<td>1</td>
<td>2</td>
<td>..</td>
<td>11.41</td>
<td>27.05</td>
<td>a Microgynon 50 ED BN</td>
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<tr>
<td></td>
<td>ETHINYLESTRAEOIOL + NORETHISTERONE</td>
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<td>24.47</td>
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<tr>
<td></td>
<td>MESTRANOL + NORETHISTERONE</td>
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<td>7.67</td>
<td>24.47</td>
<td>a Brevinor PF</td>
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<td>Progestogens and estrogens, sequential preparations</td>
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<td>2776D</td>
<td>ethinylestradiol 35 microgram + norethisterone 500 microgram tablet [48] (&amp;) ethinylestradiol 35 microgram + norethisterone 1 mg tablet [36] (&amp;) inert substance tablet [28], 112 [4 x 28]</td>
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<td>8487Q</td>
<td>etonogestrel 68 mg implant, 1</td>
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<td>36.90</td>
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<td>3118D</td>
<td>medroxyprogesterone acetate 150 mg/mL injection, 1 x 1 mL vial</td>
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<td>3.50</td>
<td>26.51</td>
<td>a Depo-Provera PF</td>
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<td>17.95</td>
<td>Noriday 28 Day PF</td>
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</tr>
</tbody>
</table>

**ANDROGENS**

3-oxoandrostenedione (4) derivatives

**TESTOSTERONE**

*Authority required*

Androgen deficiency in males with established pituitary or testicular disorders

*Authority required*

Androgen deficiency in males 40 years and older who do not have established pituitary or testicular disorders other than aging, confirmed by at least 2 morning blood samples taken on different mornings. Androgen deficiency is confirmed by testosterone less than 8 nmol per L, or 8-15 nmol per L with high LH (greater than 1.5 times the upper limit of the eugonadal reference range for young men)

*Authority required*

Micropenis, pubertal induction, or constitutional delay of growth or puberty, in males under 18 years of age

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<thead>
<tr>
<th>Code</th>
<th>Name</th>
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<th>No. of Rpts</th>
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<tr>
<td>8830R</td>
<td>testosterone 1% (50 mg/5 g) gel, 30 x 5 g sachets</td>
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<td>5</td>
<td>95.46</td>
<td>Testogel BN</td>
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<td>2341F</td>
<td>testosterone 2% (30 mg/1.5 mL actuation) transdermal solution, 60 actuations</td>
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<td>5</td>
<td>82.79</td>
<td>Axiron LY</td>
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<tr>
<td>8460G</td>
<td>testosterone 2.5 mg/24 hours patch, 60</td>
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<td>5</td>
<td>96.18</td>
<td>Androderm GN</td>
</tr>
<tr>
<td>8619P</td>
<td>testosterone 5 mg/24 hours patch, 30</td>
<td>¶1</td>
<td>5</td>
<td>96.18</td>
<td>Androderm GN</td>
</tr>
</tbody>
</table>

**TESTOSTERONE ENANTHATE**

*Authority required*

Androgen deficiency in males with established pituitary or testicular disorders

*Authority required*

Androgen deficiency in males 40 years and older who do not have established pituitary or testicular disorders other than aging, confirmed by at least 2 morning blood samples taken on different mornings. Androgen deficiency is confirmed by testosterone less than 8 nmol per L with high LH (greater than 1.5 times the upper limit of the eugonadal reference range for young men)

*Authority required*

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<td>3</td>
<td>33.82</td>
<td>Primoteston Depot BN</td>
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</table>

**TESTOSTERONE UNDECANOATE**

*Authority required*

Androgen deficiency in males with established pituitary or testicular disorders

*Authority required*

Androgen deficiency in males 40 years and older who do not have established pituitary or testicular disorders other than aging, confirmed by at least 2 morning blood samples taken on different mornings. Androgen deficiency is confirmed by testosterone less than 8 nmol per L with high LH (greater than 1.5 times the upper limit of the eugonadal reference range for young men)

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Micropenis, pubertal induction, or constitutional delay of growth or puberty, in males under 18 years of age

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<td>9004X</td>
<td>testosterone undecanoate 1 g/4 mL injection, 1 x 4 mL ampoule</td>
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<td>1</td>
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<td>Reandron 1000 BN</td>
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<td>Andriol Testocaps MK</td>
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**ESTROGENS**

_Natural and semisynthetic estrogens, plain_

**OESTRADIOL**

*Note*

Oestradiol should be used in conjunction with an oral progestogen in women with an intact uterus.

*Note*

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been...
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<tr>
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<th>Brand Name and Manufacturer</th>
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<tr>
<td>8286D</td>
<td>oestradiol 0.1% (1 mg/g) gel, 28 x 1 g sachets</td>
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<td>..</td>
<td>17.43</td>
<td>18.58</td>
<td></td>
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<tr>
<td>8126Q</td>
<td>oestradiol 100 microgram/24 hours patch, 4</td>
<td>‡1 5</td>
<td>..</td>
<td>19.47</td>
<td>20.62</td>
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<td>Climara 100 BN</td>
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<tr>
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<td>oestradiol 100 microgram/24 hours patch, 8</td>
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<td>20.62</td>
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<tr>
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<tr>
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<td>18.58</td>
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<td>Estradot 37.5 NV</td>
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<tr>
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<td>18.58</td>
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<td>Estraderm MX 50 NV</td>
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<td>18.58</td>
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<td>20.62</td>
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</table>

**OESTRADIOL**

**Note**

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

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<tr>
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<td>13.17</td>
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<td>Progynova BN</td>
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<tr>
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**OESTRIOL**

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<td>20.58</td>
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**PROGESTOGENS**

**Pregnen (4) derivatives**

**MEDROXYPROGESTERONE**

**Restricted benefit**

For Endometriosis

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<td>34.25</td>
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<td>Ralovera FZ</td>
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**MEDROXYPROGESTERONE**

**Note**

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### GENITO URINARY SYSTEM AND SEX HORMONES

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<th>Brand Name and Manufacturer</th>
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<td>2321E</td>
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<td>2</td>
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<td>14.66</td>
<td>15.81</td>
<td>Medroxyprogesterone Sandoz</td>
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<td>17.11</td>
<td>Medroxyprogesterone Sandoz</td>
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</tbody>
</table>

### Estren derivatives

**NORETHISTERONE**

**Note**

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### PROGESTOGENS AND ESTROGENS IN COMBINATION

#### Progestogens and estrogens, fixed combinations

**NORETHISTERONE ACETATE + OESTRADIOL**

**Note**

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<tr>
<td>8427M</td>
<td>oestradiol 50 microgram/24 hours + norethisterone acetate 140 microgram/24 hours patch, 8</td>
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<td>..</td>
<td>19.47</td>
<td>20.62</td>
<td>Estalis continuous 50/140</td>
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<tr>
<td>8428N</td>
<td>oestradiol 50 microgram/24 hours + norethisterone acetate 250 microgram/24 hours patch, 8</td>
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<td>5</td>
<td>..</td>
<td>19.47</td>
<td>20.62</td>
<td>Estalis continuous 50/250</td>
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</tbody>
</table>

#### Progestogens and estrogens, sequential preparations

**NORETHISTERONE ACETATE + OESTRADIOL (&) OESTRADIOL**

**Note**

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<tbody>
<tr>
<td>8425K</td>
<td>oestradiol 50 microgram/24 hours + oestadiol 50 microgram/24 hours patch [4 patches] (&amp;) oestradiol 50 microgram/24 hours patch [4 patches], 8</td>
<td>‡1</td>
<td>5</td>
<td>..</td>
<td>19.47</td>
<td>20.62</td>
<td>Estalis sequi 50/140</td>
</tr>
<tr>
<td>8426L</td>
<td>oestradiol 50 microgram/24 hours + oestadiol 50 microgram/24 hours patch [4 patches] (&amp;) oestradiol 50 microgram/24 hours patch [4 patches], 8</td>
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<td>5</td>
<td>..</td>
<td>19.47</td>
<td>20.62</td>
<td>Estalis sequi 50/250</td>
</tr>
</tbody>
</table>

### OESTRADIOL (&) OESTRADIOL + DYdrogestosterone

**Note**

Continuing Therapy Only:

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

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
<th>Premium Price for Max. Qty</th>
<th>Dispensed Price for Max. Qty</th>
<th>Maximum Recordable Value for Safety Net</th>
<th>Brand Name and Manufacturer</th>
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<tr>
<td>8244X</td>
<td>oestradiol 2 mg tablet [14] (&amp;) oestradiol 2 mg + dydrogesterone 10 mg tablet [14], 28</td>
<td>‡1</td>
<td>5</td>
<td>..</td>
<td>19.10</td>
<td>20.25</td>
<td>Femoston 2/10</td>
</tr>
</tbody>
</table>

### GONADOTROPINS AND OTHER OVULATION STIMULANTS

#### Gonadotropins

**FOLLITROPIN ALFA**

Restricted benefit

Anovulatory infertility

**Restricted benefit**

For the treatment of infertility in males due to hypogonadotrophic hypogonadism, following failure of 6 months' treatment with human chorionic...
gonadotrophin to achieve adequate spermatogenesis. Combined treatment with HCG must be given.

**Note**
Except in cases of hypopituitarism or primary amenorrhoea, the patient should have been adequately treated with clomiphene citrate and/or gonadorelin and failed to have conceived.

Women who have had apparent ovulation induced by other agents and have failed to conceive should have laparoscopic evidence that there is no other impediment to conception.

Oligomenorrhoea should have been present for at least twelve months or amenorrhoea for at least six months prior to treatment.

Patients with hyperprolactinaemia should have had appropriate surgical or medical treatment prior to treatment.

<table>
<thead>
<tr>
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<th>Name, Restriction, Manner of Administration and Form</th>
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<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>8713N</td>
<td>follitropin alfa 300 international units / 0.5 mL (21.84 microgram/0.5 mL) injection, 1 x 0.5 mL cartridge</td>
<td>3</td>
<td>5</td>
<td>..</td>
<td>*493.84</td>
<td>36.90</td>
<td>Gonal-f Pen SG</td>
</tr>
<tr>
<td>8714P</td>
<td>follitropin alfa 450 international units / 0.75 mL (32.76 microgram/0.75 mL) injection, 1 x 0.75 mL cartridge</td>
<td>3</td>
<td>5</td>
<td>..</td>
<td>*737.41</td>
<td>36.90</td>
<td>Gonal-f Pen SG</td>
</tr>
<tr>
<td>8715Q</td>
<td>follitropin alfa 900 international units / 1.5 mL (65.52 microgram/1.5 mL) injection, 1 x 1.5 mL cartridge</td>
<td>2</td>
<td>5</td>
<td>..</td>
<td>*980.94</td>
<td>36.90</td>
<td>Gonal-f Pen SG</td>
</tr>
</tbody>
</table>

**FOLLITROPIN BETA**

**Restricted benefit**
Anovulatory infertility

For the treatment of infertility in males due to hypogonadotrophic hypogonadism, following failure of 6 months' treatment with human chorionic gonadotrophin to achieve adequate spermatogenesis. Combined treatment with HCG must be given.

**Note**
Except in cases of hypopituitarism or primary amenorrhoea, the patient should have been adequately treated with clomiphene citrate and/or gonadorelin and failed to have conceived.

Women who have had apparent ovulation induced by other agents and have failed to conceive should have laparoscopic evidence that there is no other impediment to conception.

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Patients with hyperprolactinaemia should have had appropriate surgical or medical treatment prior to treatment.

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<tbody>
<tr>
<td>8565T</td>
<td>follitropin beta 300 international units/0.36 mL injection, 1 x 0.36 mL cartridge</td>
<td>3</td>
<td>5</td>
<td>..</td>
<td>*509.95</td>
<td>36.90</td>
<td>Puregon 300 IU/0.36 mL MK</td>
</tr>
<tr>
<td>8566W</td>
<td>follitropin beta 600 international units/0.72 mL injection, 1 x 0.72 mL cartridge</td>
<td>2</td>
<td>5</td>
<td>..</td>
<td>*661.40</td>
<td>36.90</td>
<td>Puregon 600 IU/0.72 mL MK</td>
</tr>
<tr>
<td>8871X</td>
<td>follitropin beta 900 international units/1.08 mL injection, 1 x 1.08 mL cartridge</td>
<td>2</td>
<td>5</td>
<td>..</td>
<td>*979.92</td>
<td>36.90</td>
<td>Puregon 900 IU/1.08 mL MK</td>
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</table>

**GONADOTROPHIN CHORIONIC HUMAN**

**Restricted benefit**
Anovulatory infertility

**Restricted benefit**
For the treatment of infertility in males due to hypogonadotrophic hypogonadism

**Restricted benefit**
For the treatment of infertility in males associated with isolated luteinising hormone deficiency

**Restricted benefit**
For the treatment of males who have combined deficiency of human growth hormone and gonadotrophins and in whom the absence of secondary sexual characteristics indicates a lag in maturation

**Restricted benefit**
For the treatment of boys over the age of 16 years who show clinical evidence of hypogonadism or delayed puberty. Treatment must not extend beyond 6 months

**Note**
Except in cases of hypopituitarism or primary amenorrhoea, the patient should have been adequately treated with clomiphene citrate and/or gonadorelin and failed to have conceived.

Women who have had apparent ovulation induced by other agents and have failed to conceive should have laparoscopic evidence that there is no other impediment to conception.

Oligomenorrhoea should have been present for at least twelve months or amenorrhoea for at least six months prior to treatment.

Patients with hyperprolactinaemia should have had appropriate surgical or medical treatment prior to treatment.
### Ovulation stimulants, synthetic

**CLOMIPHENE**

*Restricted benefit*

Anovulatory infertility

*Restricted benefit*

Patients undergoing in-vitro fertilisation

**Note**

Care must be taken to comply with the provisions of State/Territory law when prescribing clomiphene citrate.

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<tr>
<th>Code</th>
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<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>1581F</td>
<td>gonadotrophin chorionic human 1500 international units injection [3 x 1500 international units ampoules] (&amp;) inert substance diluent [3 x 1 mL ampoules], 1 pack</td>
<td>1</td>
<td>5</td>
<td>..</td>
<td>53.81</td>
<td>36.90</td>
<td>Pregnyl MK</td>
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**ANTIANDROGENS**

**Antiandrogens, plain**

### CYPROTERONE

**Authority required (STREAMLINED)**

1581

Advanced carcinoma of the prostate

**Authority required (STREAMLINED)**

121

To reduce drive in sexual deviations in males

1211R  clomiphene citrate 50 mg tablet, 10  1  5  ..  34.85  36.00  a  Clomid SW

a  Serophene SG

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<tr>
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<tbody>
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<td>8019C</td>
<td>cyproterone acetate 100 mg tablet, 50</td>
<td>1</td>
<td>5</td>
<td>..</td>
<td>99.89</td>
<td>36.90</td>
<td>a  Cyprocur 100 QA</td>
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a  Cyprostat-100 SY

a  Cyproterone AN EA

a  Cyproterone Sandoz HX

a  GenRx Cyproterone Acetate GA

a  Procur 100 GN

a  Androcur-100 BN

1270W  cyproterone acetate 50 mg tablet, 50  2  5  ..  *126.34 | 36.90 | a  Cyprocur 50 QA |

a  Cypro

a  Cyprostat SY

a  Cyproterone AN EA

a  Cyproterone Sandoz HX

a  Cyrotone ER

a  GenRx Cyproterone Acetate GX

a  Procur GN

a  Androcur BN

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<td>1269T</td>
<td>cyproterone acetate 50 mg tablet, 20</td>
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<td>5</td>
<td>..</td>
<td>31.76</td>
<td>32.91</td>
<td>a  Cyprocur 50 QA</td>
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a  Cypro

a  Cyprostat SY

a  Cyproterone AN EA

a  Cyproterone Sandoz HX

a  GenRx Cyproterone Acetate GX

a  Procur GN

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<td>5</td>
<td>..</td>
<td>31.76</td>
<td>32.91</td>
<td>a  Cyprocur 50 QA</td>
</tr>
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</table>

a  Cypro

a  Cyprostat SY

a  Cyproterone AN EA

a  Cyproterone Sandoz HX

a  GenRx Cyproterone Acetate GX

a  Procur GN

**Caution**

This drug should not be used during pregnancy as it may result in feminisation of the male foetus.
### OTHER SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM

#### Antigonadotropins and similar agents

**DANAZOL**
- **Authority required (STREAMLINED)**
- 1090
  - Endometriosis, visually proven
- **Authority required (STREAMLINED)**
- 1151
  - Hereditary angio-oedema
- **Authority required (STREAMLINED)**
- 2639
  - Short-term treatment (up to 6 months) of intractable primary menorrhagia (Treatment of this indication is limited to 6 months. See Australian Product Information)
- **Authority required (STREAMLINED)**
- 2640
  - Short-term treatment (up to 6 months) of severe benign (fibrocystic) breast disease or mastalgia associated with severe symptomatic benign breast disease in patients refractory to other treatments (Treatment of this indication is limited to 6 months. See Australian Product Information)

**Caution**
Pregnancy must be excluded prior to administration of this drug.

<table>
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<tr>
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<td>1285P</td>
<td>danazol 100 mg capsule, 100</td>
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<td>58.92</td>
<td>36.90</td>
<td>32.91</td>
<td>Azol 100 AF</td>
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<tr>
<td>1287R</td>
<td>danazol 200 mg capsule, 100</td>
<td>1</td>
<td>5</td>
<td>87.31</td>
<td>36.90</td>
<td>32.91</td>
<td>Azol 200 AF</td>
</tr>
</tbody>
</table>

**GESTRINONE**
- **Authority required (STREAMLINED)**
- 3652
  - Short-term treatment (up to 6 months) of visually proven endometriosis (only 1 course of not more than 6 months’ therapy may be prescribed)

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
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<td>8015W</td>
<td>gestrinone 2.5 mg capsule, 8</td>
<td>1</td>
<td>5</td>
<td>82.15</td>
<td>36.90</td>
<td>32.91</td>
<td>Dimetriose SW</td>
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</tbody>
</table>

#### Antiprogestogens

**MIFEPRISTONE**
- **Authority required**
  - Termination of an intra-uterine pregnancy
  - Clinical criteria:
    - The condition must be an intra-uterine pregnancy of up to 49 days of gestation, AND
    - The treatment must be in sequential combination with misoprostol 800 micrograms.
  - Treatment criteria:
    - Must be treated by a prescriber who is registered with the MS 2 Step Prescribing Program.
    - An authority prescription for misoprostol 200 microgram tablets must be sought at the time of authority application.

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

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

<table>
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<tr>
<th>Code</th>
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<th>Brand Name and Manufacturer</th>
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<td>2710P</td>
<td>mifepristone 200 mg tablet, 1</td>
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<td>320.22</td>
<td>36.90</td>
<td>32.91</td>
<td>Mifepristone Linepharma XH</td>
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### UROLOGICALS

#### Drugs for urinary frequency and incontinence

**OXYBUTYNIN**
- **Restricted benefit**
  - Detrusor overactivity in a patient who cannot tolerate oral oxybutynin, or who cannot swallow oral oxybutynin

<table>
<thead>
<tr>
<th>Code</th>
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<tr>
<td>9454N</td>
<td>oxybutynin 3.9 mg/24 hours patch, 8</td>
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<td>5</td>
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<td>36.72</td>
<td>34.20</td>
<td>Oxytrol GN</td>
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## GENITO URINARY SYSTEM AND SEX HORMONES

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<td>OXYBUTYNIN Restricted benefit</td>
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<tr>
<td>8039D</td>
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<td>5</td>
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<td>13.80</td>
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<td>OXYBUTYNIN Restricted benefit</td>
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<td>PROPANTHELINE Restricted benefit Detrusor overactivity</td>
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<td>9470K</td>
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<td>14.34</td>
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<td>PHENOXYBENZAMINE Restricted benefit Phaeochromocytoma</td>
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<td>Restricted benefit Neurogenic urinary retention</td>
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<td>1862B phenoxybenzamine hydrochloride 10 mg, 30</td>
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<td>35.63</td>
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<td>Dibenzyline GH</td>
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<td>1164.81</td>
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<td>3687 Treatment of lower urinary tract symptoms due to benign prostatic hyperplasia where treatment has been initiated by a urologist</td>
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<td>3667 Treatment, in combination with an alpha-antagonist, of lower urinary tract symptoms due to benign prostatic hyperplasia where treatment is initiated by a urologist</td>
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<td>3687 Treatment of lower urinary tract symptoms due to benign prostatic hyperplasia where treatment has been initiated by a urologist</td>
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### Continuation of Therapy Only:
- For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.
## GENITO URINARY SYSTEM AND SEX HORMONES

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### Systemic Hormonal Preparations, Excl. Sex Hormones and Insulins

#### Anterior Pituitary Lobe Hormones and Analogues

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<td>2832C</td>
<td>Tetracosactrin modified release, 1 x 1 mL ampoule</td>
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<td>*71.61</td>
<td>36.90</td>
<td>Synacthen Depot 1 mg/1 mL NV</td>
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**Thyrotropin**

**Thyrotropin Alfa**

*Authority required (STREAMLINED)*

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<td>3193</td>
<td>Ablation of thyroid remnant tissue, in combination with radioactive iodine, in a post thyroidectomy patient without known metastatic disease</td>
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<tr>
<td>2700D</td>
<td>Thyrotropin alfa 900 microgram injection, 2 x 900 microgram vials</td>
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<td>1901.76</td>
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#### Posterior Pituitary Lobe Hormones

**Vasopressin and analogues**

**Desmopressin**

*Authority required (STREAMLINED)*

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<td>Desmopressin 120 microgram wafer: sublingual, 30</td>
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<td>71.19</td>
<td>36.90</td>
<td>Minirin Melt FP</td>
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<tr>
<td>8975J</td>
<td>Desmopressin 240 microgram wafer: sublingual, 30</td>
<td>1</td>
<td>5</td>
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<td>116.28</td>
<td>36.90</td>
<td>Minirin Melt FP</td>
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**Desmopressin**

*Authority required (STREAMLINED)*

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<td>1678</td>
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<tr>
<td>8711L</td>
<td>Desmopressin acetate 10 microgram/actuation nasal spray, 60 actuations</td>
<td>2</td>
<td>5</td>
<td>..</td>
<td>*161.38</td>
<td>36.90</td>
<td>Minirin Nasal Spray FP</td>
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<tr>
<td>2129C</td>
<td>Desmopressin acetate 100 microgram/mL nasal drops, 2.5 mL</td>
<td>5</td>
<td>5</td>
<td>..</td>
<td>*161.51</td>
<td>36.90</td>
<td>Minirin FP</td>
</tr>
<tr>
<td>8662X</td>
<td>Desmopressin acetate 200 microgram tablet, 30</td>
<td>3</td>
<td>5</td>
<td>..</td>
<td>*180.25</td>
<td>36.90</td>
<td>Minirin FP</td>
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</tbody>
</table>
### Systemic Hormonal Preparations, Excl. Sex Hormones and Insulins

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<tr>
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<td>8663Y</td>
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<td>64.59</td>
<td></td>
<td>36.90</td>
<td>Minirin FP</td>
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</table>

**Note**

- Not to be used in preference to enuresis alarms.
- Desmopressin nasal spray may be associated with an increased risk of hyponatraemia compared to the oral formulations.

### Hypothalamic Hormones

**Gonadotropin-releasing hormones**

- **Nafarelin**
  - Authority required
  - Initial treatment (up to 6 months) of visually proven endometriosis

- **Authority required**
  - Subsequent treatment (up to 6 months) of visually proven endometriosis, where 2 years or more have elapsed since the end of the previous course and where a recent bone density assessment has been made. The date of the assessment must be provided

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<td>2962X</td>
<td>Nafarelin 200 microgram/actuation nasal spray</td>
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<td>132.13</td>
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#### Corticosteroids for Systemic Use

**Corticosteroids for Systemic Use, Plain**

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

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<td>1433K</td>
<td>Fludrocortisone acetate 100 microgram/actuation</td>
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<td>*46.84</td>
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</table>

- **Glucocorticoids**
  - **Betamethasone Acetate + Betamethasone Sodium Phosphate**
  - **Restricted benefit**
    - Alopecia areata
    - For local intra-articular or peri-articular infiltration
    - Granulomata, dermal
    - Keloid
    - Lichen planus hypertrophic
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<td>Lupus erythematosus, chronic discoid</td>
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<td>Restricted benefit</td>
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<td>Restricted benefit</td>
<td>Uveitis</td>
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<td>2694T NP</td>
<td>betamethasone (as acetate) 2.71 mg/mL + betamethasone (as sodium phosphate) 2.96 mg/mL injection, 5 x 1 mL ampoules</td>
<td>1 .. ..</td>
<td>25.34</td>
<td>26.49</td>
<td>Celestone Chronodose MK</td>
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<tr>
<td><strong>BETAMETHASONE ACETATE + BETAMETHASONE SODIUM PHOSPHATE</strong></td>
<td><strong>Restricted benefit</strong> For local intra-articular or peri-articular infiltration</td>
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<td>No. of Rpts</td>
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<td>Maximum Recordable Value for Safety Net $</td>
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<td>1500Y</td>
<td>hydrocortisone 20 mg tablet, 60</td>
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<td>17.98</td>
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<td>6</td>
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<td>*40.60</td>
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<td>1511M</td>
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<td>*64.60</td>
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<td>methylprednisolone Powder for injection 1 g (as sodium succinate), 1</td>
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<td>70.47</td>
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<td>Methylpred AS</td>
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</table>

**HYDROCORTISONE**

**Note**

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

**METHYLPREDNISOLONE**

**Note**

Pharmaceutical benefits that have the form methylprednisolone powder for injection 1 g (as sodium succinate) and pharmaceutical benefits that have the form methylprednisolone powder for injection 1 g (as sodium succinate) with diluent are equivalent for the purposes of substitution.

**METHYLPREDNISOLONE**

**Note**

Pharmaceutical benefits that have the form methylprednisolone powder for injection 40 mg (as sodium succinate) and pharmaceutical benefits that have the form methylprednisolone powder for injection 40 mg (as sodium succinate) with diluent are equivalent for the purposes of substitution.

**METHYLPREDNISOLONE**

**Restricted benefit**

For local intra-articular or peri-articular infiltration
<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>Dispensed Price for Max. Qty $</th>
<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1928L</td>
<td>methylprednisolone acetate 40 mg/mL injection, 5 x 1 mL vials</td>
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<td>23.96</td>
<td>25.11 a</td>
<td>Depo-Nisolone</td>
<td>FZ</td>
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<td>3152X</td>
<td>prednisolone 1 mg tablet, 100</td>
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<td>LN</td>
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<td>1916W</td>
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<td>5</td>
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<td>15.04 16.19 a</td>
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<td>For local intra-articular or peri-articular infiltration</td>
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<td>Lichen planus hypertrophic</td>
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<td>Lichen simplex chronicus</td>
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<td>Lupus erythematosus, chronic discoid</td>
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<td></td>
<td>For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.</td>
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<tr>
<td>2990J</td>
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<td>25.34</td>
<td>26.49 Kenacort-A10</td>
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<td>Brand Name and Manufacturer</td>
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<td>5233K</td>
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<td>..</td>
<td>25.34</td>
<td>26.49</td>
<td>Kenacort-A10 QA</td>
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**THYROID THERAPY**

**THYROID PREPARATIONS**

**Thyroid hormones**

**LIOTHYRONINE**

**Authority required (STREAMLINED)**

1219

Management of patients with thyroid cancer

**Authority required (STREAMLINED)**

1858

Replacement therapy for hypothyroid patients who have documented intolerance to thyroxine sodium

**Authority required (STREAMLINED)**

1859

Replacement therapy for hypothyroid patients who have documented resistance to thyroxine sodium

**Authority required (STREAMLINED)**

1182

Initiation of thyroid therapy in severely hypothyroid patients

**Note**

Continuing Therapy Only:

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

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<tr>
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<td>2318B</td>
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<td>83.87</td>
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**THYROXINE**

**Note**

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<td>25.47</td>
<td>Eutroxig FM</td>
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<tr>
<td>2173J</td>
<td>thyroxine sodium 200 microgram tablet, 200</td>
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<td>1</td>
<td>..</td>
<td>27.35</td>
<td>28.50</td>
<td>Eutroxig FM</td>
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<tr>
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<td>1</td>
<td>..</td>
<td>23.71</td>
<td>24.86</td>
<td>Eutroxig FM</td>
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<tr>
<td>9287T</td>
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<td>1</td>
<td>..</td>
<td>24.36</td>
<td>25.51</td>
<td>Eutroxig FM</td>
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</tbody>
</table>

**ANTITHYROID PREPARATIONS**

**Thiouracils**

**PROPYLTHIOURACIL**

**Note**

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<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>1955X</td>
<td>propylthiouracil 50 mg tablet, 100</td>
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<td>2</td>
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<td>*49.98</td>
<td>36.90</td>
<td>PTU PL</td>
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</table>

**Sulfur-containing imidazole derivatives**

**CARBIMAZOLE**

**Note**
CONTINUING THERAPY ONLY:

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

1153Q

Carbimazole 5 mg tablet, 100

Dispensed Price for Max. Qty Premium $ 31.38
No. of Rpts Maximum Qty 2 32.53

Brand Name and Manufacturer Carbimazol ARISTO

PQ Neo-Mercazol LM

GLUCAGON HYDROCHLORIDE

Glycogenolytic hormones

1449G

Glucagon hydrochloride 1 mg injection [1 x 1 mg vial] (6) inert substance diluent [1 x 1 mL syringe], 1 pack

Dispensed Price for Max. Qty Premium $ 49.44
No. of Rpts Maximum Qty 1 36.90

Brand Name and Manufacturer GlucaGen Hypokit

NO

5105Q

Glucagon hydrochloride 1 mg injection [1 x 1 mg vial] (6) inert substance diluent [1 x 1 mL syringe], 1 pack

Dispensed Price for Max. Qty Premium $ 49.44
No. of Rpts Maximum Qty 1 36.90

Brand Name and Manufacturer GlucaGen Hypokit

NO

CALCIUM HOMEOSTASIS

PARATHYROID HORMONES AND ANALOGUES

Parathyroid hormones and analogues

TERIPARATIDE

Authority required

Severe established osteoporosis

Treatment Phase: Initial treatment

Clinical criteria:

Patient must be at very high risk of fracture,

AND

Patient must have a bone mineral density (BMD) T-score of -3.0 or less,

AND

Patient must have had 2 or more fractures due to minimal trauma,

AND

Patient must have experienced at least 1 symptomatic new fracture after at least 12 months continuous therapy with an anti-resorptive agent at adequate doses,

AND

The treatment must be the sole PBS-subsidised agent,

AND

The treatment must not exceed a lifetime maximum of 18 months therapy.

Treatment criteria:

Must be treated by a specialist; OR

Must be treated by a consultant physician.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

If treatment with anti-resorptive therapy is contraindicated according to the relevant TGA-approved Product Information, details of the contraindication must be documented in the patient’s medical record at the time treatment with teriparatide is initiated.

If an intolerance of a severity necessitating permanent treatment withdrawal develops during the relevant period of use of one anti-resorptive agent, alternate anti-resorptive agents must be trialled so that the patient achieves the minimum requirement of 12 months continuous therapy. Details must be documented in the patient’s medical record at the time treatment with teriparatide is initiated.

Anti-resorptive therapies for osteoporosis and their adequate doses which will be accepted for the purposes of administering this restriction are alendronate sodium 10 mg per day or 70 mg once weekly, risedronate sodium 5 mg per day or 35 mg once weekly or 150 mg once monthly, raloxifene hydrochloride 60 mg per day (women only), denosumab 60 mg once every 6 months, strontium ranelate 2 g per day and zoledronic acid 5 mg per annum.

Details of prior anti-resorptive therapy, fracture history including the date(s), site(s), the symptoms associated with the fracture(s) which developed after at least 12 months continuous anti-resorptive therapy and the score of the qualifying BMD measurement must be provided at the time of application.
### Systemic Hormonal Preparations, Excl. Sex Hormones and Insulins

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
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</tr>
</thead>
</table>

**ANTI-PARATHYROID AGENTS**

**Calcitonin preparations**

**SALCATONIN**

**Authority required (STREAMLINED)**

- **3256**
  - Symptomatic Paget disease of bone

**Authority required (STREAMLINED)**

- **1412**
  - Treatment initiated in a hospital (in-patient or out-patient) of hypercalcaemia

**Note**

The maximum quantities for salcatonin shown represent the number of individual ampoules and NOT multiples of the manufacturer’s packs. The pack size for both strengths is five ampoules.

**Note**

Continuing Therapy Only:

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

**Other anti-parathyroid agents**

**CINACALCET**

**Authority required (STREAMLINED)**

- **3673**
  - Maintenance therapy, following initiation and stabilisation of treatment with cinacalcet, of a patient with chronic kidney disease on dialysis who has a decrease of at least 30% in iPTH concentrations after 6 months treatment

**Authority required (STREAMLINED)**

- **3672**
  - Maintenance therapy, following initiation and stabilisation of treatment with cinacalcet, of a patient with chronic kidney disease on dialysis who has iPTH greater than 15 pmol per L and an (adjusted) serum calcium concentration of less than 2.6 mmol per L after 6 months treatment

**Note**

During the titration phase, intact PTH should be monitored 4 weekly (measured at least 12 hours post dose) and dose titrated until an appropriate...

### Note

Details of accepted toxicities including severity can be found on the Department of Human Services website at www.humanservices.gov.au.

**Note**

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

**Note**

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

**Note**

Special Pricing Arrangements apply.

**Authority required**

Severe established osteoporosis

Treatment Phase: Continuing treatment

**Clinical criteria:**

Patient must have previously been issued with an authority prescription for this drug.

**AND**

The treatment must not exceed a lifetime maximum of 18 months therapy.

**Note**

Up to a maximum of 18 pens will be reimbursed through the PBS.

**Note**

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

**Note**

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

**Note**

Special Pricing Arrangements apply.

**9411H**

- teriparatide 20 microgram/dose injection, 1 x 2.4 mL cartridge
  - 1
  - 5
  - ... 438.71 36.90
  - Forteo

**LY**
iPTH concentration is achieved. During the titration phase, approval will be limited to sufficient supply for 4 weeks treatment at a time, with doses between 30 and 180 mg per day according to the patient’s response and tolerability.

During the maintenance phase, approval will be limited to provide sufficient quantity for 4 weeks treatment up to a maximum of 6 months supply for doses between 30 and 180 mg per day according to the patient’s response and tolerability. Intact PTH should be monitored quarterly (measured at least 12 hours post dose) and dose adjusted as necessary to maintain an appropriate iPTH concentration.

**Note**
Special Pricing Arrangements apply.

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

<table>
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<th>Brand Name and Manufacturer</th>
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# ANTIINFECTIVES FOR SYSTEMIC USE

## ANTIBACTERIALS FOR SYSTEMIC USE

### TETRACYCLINES

**Tetracyclines**

**DOXYCYCLINE**

**Restricted benefit**

Urethritis

**Note**

Pharmaceutical benefits that have the forms doxycycline tablet 100 mg (as hydrochloride), doxycycline tablet 100 mg (as monohydrate) and doxycycline capsule: modified release 100 mg (as hydrochloride) are equivalent for the purposes of substitution.

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<td>4 ..</td>
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<td>*15.84</td>
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**DOXYCYCLINE**

**Restricted benefit**

Pelvic inflammatory disease

**Note**

Pharmaceutical benefits that have the forms doxycycline tablet 100 mg (as hydrochloride), doxycycline tablet 100 mg (as monohydrate) and doxycycline capsule: modified release 100 mg (as hydrochloride) are equivalent for the purposes of substitution.

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<td></td>
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<td>a Terry White Chemists Doxycycline</td>
</tr>
</tbody>
</table>

**DOXYCYCLINE**

*Restricted benefit*

**Bronchiectasis**

**Population criteria:**
Patient must be aged 8 years or older.

*Restricted benefit*

**Chronic bronchitis**

**Population criteria:**
Patient must be aged 8 years or older.

*Restricted benefit*

**Severe acne**

**Note**
Pharmaceutical benefits that have the forms doxycycline tablet 50 mg (as hydrochloride), doxycycline tablet 50 mg (as monohydrate) and doxycycline capsule: modified release 50 mg (as hydrochloride) are equivalent for the purposes of substitution.

| 2707L    | doxycycline 50 mg capsule: modified release, 25 capsules                               | 1                | 5           | 1.63      | 10.66               | 10.18                          |                                 | a Mayne Pharma Doxycycline YT        |
| NP       |                                                                                         |                  |             |           |                     |                                 |                                          | a Doryx YN                          |
|          |                                                                                         |                  |             |           |                     |                                 |                                          | a Doxy-50 GN                        |
|          |                                                                                         |                  |             |           |                     |                                 |                                          | a Doxyl 50 AF                       |
|          |                                                                                         |                  |             |           |                     |                                 |                                          | a Chem mart Doxycycline CH          |
|          |                                                                                         |                  |             |           |                     |                                 |                                          | a Doxycycline Sandoz HX             |
|          |                                                                                         |                  |             |           |                     |                                 |                                          | a Frakas QA                         |
|          |                                                                                         |                  |             |           |                     |                                 |                                          | a GenRx Doxycycline GX              |
|          |                                                                                         |                  |             |           |                     |                                 |                                          | a Terry White Chemists Doxycycline   |
| 2711Q    | doxycycline 50 mg tablet, 25                                                            | 1                | 5           | 3.93      | 12.96               | 10.18                          |                                 | a Mayne Pharma Doxycycline YT        |
| NP       |                                                                                         |                  |             |           |                     |                                 |                                          | a Doryx YN                          |
|          |                                                                                         |                  |             |           |                     |                                 |                                          | a Doxy-50 GN                        |
|          |                                                                                         |                  |             |           |                     |                                 |                                          | a Doxyl 50 AF                       |
|          |                                                                                         |                  |             |           |                     |                                 |                                          | a Chem mart Doxycycline CH          |
|          |                                                                                         |                  |             |           |                     |                                 |                                          | a Doxycycline Sandoz HX             |
|          |                                                                                         |                  |             |           |                     |                                 |                                          | a Frakas QA                         |
|          |                                                                                         |                  |             |           |                     |                                 |                                          | a GenRx Doxycycline GX              |
|          |                                                                                         |                  |             |           |                     |                                 |                                          | a Terry White Chemists Doxycycline   |
| 9106G    | doxycycline 50 mg tablet, 25                                                            | 1                | 5           | 9.03      | 10.18               |                                 |                                          | a Mayne Pharma Doxycycline YT        |
| NP       |                                                                                         |                  |             |           |                     |                                 |                                          | a Doryx YN                          |
|          |                                                                                         |                  |             |           |                     |                                 |                                          | a Doxy-50 GN                        |
|          |                                                                                         |                  |             |           |                     |                                 |                                          | a Doxyl 50 AF                       |
|          |                                                                                         |                  |             |           |                     |                                 |                                          | a Chem mart Doxycycline CH          |
|          |                                                                                         |                  |             |           |                     |                                 |                                          | a Doxycycline Sandoz HX             |
|          |                                                                                         |                  |             |           |                     |                                 |                                          | a Frakas QA                         |
|          |                                                                                         |                  |             |           |                     |                                 |                                          | a GenRx Doxycycline GX              |
|          |                                                                                         |                  |             |           |                     |                                 |                                          | a Terry White Chemists Doxycycline   |

**MINOCYCLINE**

*Restricted benefit*

Severe acne not responding to other tetracyclines

**Caution**
There are concerns about the incidence of benign intracranial hypertension associated with this drug.

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

| 1616C    | minocycline 50 mg tablet, 60                                                           | 1                | 5           | 15.39     | 16.54               |                                 |                                          | a Akamin 50 AF                      |
| NP       |                                                                                         |                  |             |           |                     |                                 |                                          | a Minomycin-50 QA                    |

**BETA-LACTAM ANTIBACTERIALS, PENICILLINS**

*Penicillins with extended spectrum*

**AMOXICILLIN**

*Restricted benefit*

Acute exacerbations of chronic bronchitis

<p>| 8581P    | amoxycillin 1 g tablet, 14                                                            | 1                | 1           | 8.58      | 9.73                | 9.73                           |                                 | a Amoxycillin Sandoz BG             |
| NP       |                                                                                         |                  |             |           |                     |                                 |                                          | a Maxamox SZ                        |</p>
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<td>1888J NP</td>
<td>amoxicillin 100 mg/mL oral liquid: powder for, 20 mL</td>
<td>‡1 1</td>
<td>0.61</td>
<td>#14.23</td>
<td>15.12</td>
<td>Amoxil</td>
<td>AS</td>
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### Antiinfectives for Systemic Use

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<th>Dispensed Price for Max. Qty $</th>
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### Beta-lactamase sensitive penicillins

#### BENZATHINE BENZYL-PENICILLIN

- BENZATHINE BENZYL-PENICILLIN Injection 900 mg in 2.3 mL single use pre-filled syringe, 10
- BENZATHINE BENZYL-PENICILLIN Injection 900 mg in 2.3 mL single use pre-filled syringe, 10

#### BENZYL-PENICILLIN

- benzylpenicillin 3 g injection, 1 x 3 g vial
- benzylpenicillin 3 g injection, 1 x 3 g vial
- benzylpenicillin 600 mg injection, 1 x 600 mg vial
- benzylpenicillin 600 mg injection, 1 x 600 mg vial

#### PHENOXYMETHYLPENICILLIN

- phenoxymethylpenicillin 125 mg/5 mL oral liquid: powder for, 100 mL
- phenoxymethylpenicillin 125 mg/5 mL oral liquid: powder for, 100 mL
- phenoxymethylpenicillin 150 mg/5 mL oral liquid, 100 mL
- phenoxymethylpenicillin 150 mg/5 mL oral liquid, 100 mL
- phenoxymethylpenicillin 250 mg capsule, 50
- phenoxymethylpenicillin 250 mg capsule, 50
- phenoxymethylpenicillin 250 mg tablet, 25
- phenoxymethylpenicillin 250 mg tablet, 25
- phenoxymethylpenicillin 250 mg tablet, 25
- phenoxymethylpenicillin 250 mg tablet, 25

#### PHENOXYMETHYLPENICILLIN

**Restricted benefit**

- Prophylaxis of recurrent streptococcal infections (including rheumatic fever)

- phenoxymethylpenicillin 250 mg

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*Note: The table includes antiinfectives for systemic use, with information on code, name, restriction, manner of administration, form, maximum quantity, no. of reports, premium, dispensed price for max. qty, maximum recordable value for safety net, and brand name and manufacturer.*

**Beta-lactamase resistant penicillins**

- **Dicloxacillin**: Serious staphylococcal infections
  - **Restricted benefit**
  - **Caution**: Severe cholestatic hepatitis has been reported with this drug. Significant risk factors are age, particularly greater than 55 years, and duration of treatment longer than 14 days.

- **Flucloxacillin**: Serious staphylococcal infections
  - **Caution**: Severe cholestatic hepatitis has been reported with this drug. Significant risk factors are age, particularly greater than 55 years, and duration of treatment longer than 14 days.
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</table>

**Combination of penicillins, incl. beta-lactamase inhibitors**

**AMOXICILLIN + CLAVULANIC ACID**

**Restricted benefit**

Infections where resistance to amoxycillin is suspected

**Restricted benefit**

Infections where resistance to amoxycillin is proven

**Caution**

Hepatotoxicity has been reported with this drug.
### ANTIINFECTIVES FOR SYSTEMIC USE

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**TICARcILLIN + CLAVULANIC ACID**

**Restricted benefit**

Infections where positive bacteriological evidence confirms that this antibiotic is an appropriate therapeutic agent

**Restricted benefit**

Septicaemia, suspected

**Restricted benefit**

Septicaemia, proven

**Note**

Shared Care Model:

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

10113G | ticarcillin 3 g + clavulanic acid 100 mg injection, 1 x 3.1 g vial | 10 | ... | *163.76 | 36.90 | Timentin | AS |

**Ticarcillin + Clavulanic Acid**

**Restricted benefit**

Infections where positive bacteriological evidence confirms that this antibiotic is an appropriate therapeutic agent

10125X | ticarcillin 3 g + clavulanic acid 100 mg injection, 1 x 3.1 g vial | 10 | ... | *163.76 | 36.90 | Timentin | AS |
### OTHER BETA-LACTAM ANTIBACTERIALS

#### First-generation cephalosporins

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**CEPHALEXIN**

*Authority required (STREAMLINED)*

4243

Prophylaxis of urinary tract infection

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### CEPHALOTIN

**Restricted benefit**

Infections where positive bacteriological evidence confirms that this antibiotic is an appropriate therapeutic agent

**Restricted benefit**

Septicaemia, suspected

**Restricted benefit**

Septicaemia, proven

**Note**

For item codes 1257E and 1797N, pharmaceutical benefits that have the form powder for injection 1 g are equivalent for the purposes of substitution.

**Note**

Shared Care Model:

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

1257E  cephalosin 1 g injection, 10 x 1 g vials | 1 | .. | 17.02 | 18.17 | a Cefazolin Sandoz SZ
1797N  cephalosin 1 g injection, 5 x 1 g vials | 2 | .. | 17.02 | 18.17 | a Cefazolin-AFT AE

### CEPHAZOLIN

**Restricted benefit**

Cellulitis

**Note**

For item codes 5478H and 1799Q, pharmaceutical benefits that have the form powder for injection 1 g are equivalent for the purposes of substitution.

5478H  cephalosin 1 g injection, 10 x 1 g vials | 1 | .. | 17.02 | 18.17 | a Cefazolin Sandoz SZ
1799Q  cephalosin 1 g injection, 5 x 1 g vials | 2 | .. | 17.02 | 18.17 | a Cefazolin-AFT AE

### CEPHAZOLIN

**Restricted benefit**

Cellulitis

**Note**

For item codes 5479J and 5477G, pharmaceutical benefits that have the form powder for injection 1 g are equivalent for the purposes of substitution.

5479J  cephalosin 2 g injection, 1 x 2 g vial | 10 | .. | 30.26 | 31.41 | a Cefazolin Sandoz SZ
5477G  cephalosin 500 mg injection, 5 x 500 mg vials | 2 | .. | 14.46 | 15.61 | a Cefazolin Alphapharm AE

### CEPHAZOLIN

**Restricted benefit**

Infections where positive bacteriological evidence confirms that this antibiotic is an appropriate therapeutic agent

**Restricted benefit**

Septicaemia, suspected

**Restricted benefit**

Septicaemia, proven

**Note**

Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised
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### Second-generation cephalosporins

#### CEFACLOR

**Caution**

Serum sickness-like reactions have been reported with this drug, especially in children.

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### ANTIINFECTIVES FOR SYSTEMIC USE

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**Third-generation cephalosporins**

**CEFOTAXIME**

**Restricted benefit**

Infections where positive bacteriological evidence confirms that this antibiotic is an appropriate therapeutic agent

**Restricted benefit**

Septicaemia, suspected

**Restricted benefit**

Septicaemia, proven

**Note**

For item codes 1085D and 1758M, pharmaceutical benefits that have the form powder for injection 1 g are equivalent for the purposes of substitution.

**Note**

Shared Care Model:

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

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**CEFOTAXIME**

**Restricted benefit**

Infections where positive bacteriological evidence confirms that this antibiotic is an appropriate therapeutic agent

**Note**

For item codes 5048Q and 1768C, pharmaceutical benefits that have the form powder for injection 1 g are equivalent for the purposes of substitution.

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**CEFOTAXIME**

**Restricted benefit**

Infections where positive bacteriological evidence confirms that this antibiotic is an appropriate therapeutic agent

**Restricted benefit**

Septicaemia, suspected

**Restricted benefit**

Septicaemia, proven

**Note**

For item codes 1086E and 1759N, pharmaceutical benefits that have the form powder for injection 2 g are equivalent for the purposes of substitution.

**Note**

Shared Care Model:
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<td>For item codes 1784X and 1788D, pharmaceutical benefits that have the form powder for injection 1 g are equivalent for the purposes of substitution.</td>
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<td>1785Y</td>
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### Antiinfectives for Systemic Use

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<td>14.01</td>
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<td>9058R</td>
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<td>..</td>
<td>7.98</td>
<td>9.13</td>
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</tbody>
</table>

**Fourth-generation cephalosporins**

**CEFEPI**

*Authority required*

Treatment of febrile neutropenia

**Note**

Shared Care Model:

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

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<tr>
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<td>Cefepime Sandoz SZ</td>
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<td>DBL Cefepime HH</td>
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<td>8316Q</td>
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<td>DBL Cefepime HH</td>
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**Sulfonamides and trimethoprim**

*Trimethoprim and derivatives*

**TRIMETHOPRIM**

*Authority required [STREAMLINED]*

4243

Prophylaxis of urinary tract infection

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>Dispensed Price for Max. Qty $</th>
<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>2666H</td>
<td>trimethoprim 300 mg tablet, 7</td>
<td>2</td>
<td>2</td>
<td>..</td>
<td>*10.68</td>
<td>11.83</td>
<td>Alprim AF</td>
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<td>Triprim QA</td>
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<td>2922T</td>
<td>trimethoprim 300 mg tablet, 7</td>
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<td>1</td>
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<td>8.72</td>
<td>9.87</td>
<td>Alprim AF</td>
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**Combinations of sulfonamides and trimethoprim, incl. derivatives**

**TRIMETHOPRIM + sulfamethoxazole**

*Caution*

There is an increased risk of severe adverse reactions with this combination in the elderly.

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
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<th>Brand Name and Manufacturer</th>
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<tr>
<td>2951H</td>
<td>trimethoprim 160 mg + sulfamethoxazole 800 mg tablet, 10</td>
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<td>9.58</td>
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<td></td>
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<td>3390K</td>
<td>trimethoprim 160 mg + sulfamethoxazole 800 mg tablet, 10</td>
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<td>..</td>
<td>..</td>
<td>*3.90</td>
<td>13.48</td>
<td>Bactrim DS RO</td>
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<td></td>
<td>Resprim Forte AF</td>
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<tr>
<td>3103H</td>
<td>trimethoprim 40 mg/5 mL + sulfamethoxazole 200 mg/5 mL oral liquid, 100 mL</td>
<td>1</td>
<td>1</td>
<td>..</td>
<td>9.27</td>
<td>10.42</td>
<td>Bactrim RO</td>
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<tr>
<td>3391L</td>
<td>trimethoprim 40 mg/5 mL +</td>
<td>1</td>
<td>..</td>
<td>..</td>
<td>*4.25</td>
<td>13.52</td>
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### ANTIINFECTIVES FOR SYSTEMIC USE

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

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<td>0.25</td>
<td>13.52</td>
<td>10.42</td>
<td>Seprin QA</td>
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### MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS

#### Macrolides

**AZITHROMYCIN**

**Restricted benefit**

Trachoma

**Note**

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

<table>
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<tr>
<th>Code</th>
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<td>..</td>
<td>#23.70</td>
<td>25.20</td>
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<td>8336R</td>
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<td>2</td>
<td>..</td>
<td>16.26</td>
<td>17.41</td>
<td>APO-Azithromycin TX</td>
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<tr>
<td>NP</td>
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**AZITHROMYCIN**

**Restricted benefit**

Uncomplicated urethritis due to Chlamydia trachomatis

**Restricted benefit**

Uncomplicated cervicitis due to Chlamydia trachomatis

**Note**

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

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<td>APO-Azithromycin TX</td>
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#### CLARITHROMYCIN

**Restricted benefit**

Bordetella pertussis

**Restricted benefit**

Atypical mycobacterial infections

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<th>Code</th>
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<td>12.02</td>
<td>APO-Clarithromycin TX</td>
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<td>NP</td>
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**CLARITHROMYCIN**

**Restricted benefit**

Atypical mycobacterial infections

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<td>clarithromycin 250 mg/5 mL oral liquid: powder for, 50 mL</td>
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<td>Klacid AB</td>
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<td>1404X NP</td>
<td>erythromycin 250 mg capsule: enteric, 25</td>
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<td>1</td>
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<td>11.03</td>
<td>12.18</td>
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<td>erythromycin 250 mg capsule: enteric, 25</td>
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<td>11.03</td>
<td>12.18</td>
<td>Mayne Pharma Erythromycin YT</td>
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<td>..</td>
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<td>16.41</td>
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<td>erythromycin (as ethylsuccinate) 200 mg/5 mL oral liquid: powder for, 100 mL</td>
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<td>16.41</td>
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<td>13.55</td>
<td>E-Mycin 400 AF</td>
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<td>2428T NP</td>
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<td>‡1</td>
<td>1</td>
<td>..</td>
<td>#16.42</td>
<td>17.92</td>
<td>E-Mycin 400 AF</td>
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<tr>
<td>3337P DP</td>
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<td>‡1</td>
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<td>..</td>
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<td>17.92</td>
<td>E-Mycin 400 AF</td>
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<td>1397M NP</td>
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*Note: "‡" denotes a restriction.*
## Antiinfectives for Systemic Use

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### Lincosamides

#### CLINDAMYCIN

**Restricted benefit**

Gram-positive coccal infections where these cannot be safely and effectively treated with a penicillin

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#### LINCOMYCIN

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### Aminoglycoside Antimicrobials

#### Other aminoglycosides

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#### TOBRAMYCIN

**Authority required (STREAMLINED)**

Proven Pseudomonas aeruginosa infection

Clinical criteria:

Patient must have cystic fibrosis,
Patient must have been assessed for bronchial hyperresponsiveness as per the TGA-approved Product Information, with a negative test result, AND

Patient must be participating in a four week trial of tobramycin inhalation powder and will be assessed for ability to tolerate the dry powder formulation in order to qualify for continued PBS-subsidised therapy. The trial commencement date must be documented in the patient’s medical records.

Population criteria:
Patient must be 6 years of age or older.

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

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

Note
Special Pricing Arrangements apply.

10066T
tobramycin 28 mg inhalation, 224 capsules
1 2 1 2549.70 36.90 TOBI podhaler NV

**TOBRAMYCIN**
**Authority required (STREAMLINED)**

4513
Proven Pseudomonas aeruginosa infection

Treatment Phase: Continuing treatment

Clinical criteria:
Patient must have cystic fibrosis, AND

Patient must have previously been issued with an authority prescription for tobramycin inhalation capsules, AND

Patient must have demonstrated ability to tolerate the dry powder formulation following the initial 4-week treatment period, as agreed by the patient, the patient’s family (in the case of paediatric patients) and the treating physician(s).

Population criteria:
Patient must be 6 years of age or older.

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

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

Note
Special Pricing Arrangements apply.

10074F
tobramycin 28 mg inhalation, 224 capsules
1 2 1 2549.70 36.90 TOBI podhaler NV

**TOBRAMYCIN**
**Authority required (STREAMLINED)**

3842
Management of a proven Pseudomonas aeruginosa infection in a patient with cystic fibrosis

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

Note
Special Pricing Arrangements apply.

5442K
tobramycin 300 mg/5 mL inhalation: solution, 56 x 5 mL ampoules
1 2 1 2137.70 36.90 Tobi NV

**TOBRAMYCIN**
**Restricted benefit**

Systemic treatment of Pseudomonas aeruginosa infection in a patient with cystic fibrosis

9480Y NP
tobramycin 500 mg/5 mL injection, 10 x 5 mL vials
1 1 1 357.71 36.90 Tobra-Day PL

**TOBRAMYCIN**
**Restricted benefit**
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**QUINOLONE ANTIBACTERIALS**

**Fluoroquinolones**

**CIPROFLOXACIN**

**Authority required**
Respiratory tract infection proven or suspected to be caused by Pseudomonas aeruginosa in severely immunocompromised patients

**Authority required**
Bacterial gastroenteritis in severely immunocompromised patients

**Authority required**
Treatment of infections proven to be due to Pseudomonas aeruginosa or other gram-negative bacteria resistant to all other oral antimicrobials

**Authority required**
Treatment of joint and bone infections, epididymo-orchitis, prostatitis or perichondritis of the pinna, suspected or proven to be caused by gram-negative bacteria or gram-positive bacteria resistant to all other appropriate antimicrobials

**Authority required**
Gonorrhoea

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## Antiinfectives for Systemic Use

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**Note:**
Pharmaceutical benefits that have the form metronidazole 500 mg/100 mL (0.5%) injection, 10 x 100 mL bags and pharmaceutical benefits that have the form metronidazole 500 mg/100 mL (0.5%) injection, 5 x 100 mL bags are equivalent for the purposes of substitution.
## ANTIINFECTIVES FOR SYSTEMIC USE

### Restricted benefit

**Acute anaerobic sepsis**

**Treatment criteria:**

Must be treated in a hospital.

**Note**

Pharmaceutical benefits that have the form metronidazole 500 mg/100 mL (0.5%) injection, 10 x 100 mL bags and pharmaceutical benefits that have the form metronidazole 500 mg/100 mL (0.5%) injection, 5 x 100 mL bags are equivalent for the purposes of substitution.

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<td><strong>a</strong></td>
<td><strong>21.60</strong></td>
<td><strong>22.75</strong></td>
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<td>2298Y</td>
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<td><strong>a</strong>3.00</td>
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<td><strong>12.28</strong></td>
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#### Nitrofuran derivatives

**NITROFURANTOIN**

**Caution**

Nitrofurantoin may cause peripheral neuritis and severe pulmonary reactions.

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<td>24.00</td>
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#### Other antibacterials

**HEXAMINE HIPPURATE**

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## ANTIMYCOTICS FOR SYSTEMIC USE

### Triazole derivatives

**FLUCONAZOLE**

**Authority required (STREAMLINED)**

3615

Treatment of cryptococcal meningitis

**Authority required (STREAMLINED)**

3616

Maintenance therapy in patients with cryptococcal meningitis and immunosuppression

**Authority required (STREAMLINED)**

3613

Treatment of oropharyngeal candidiasis in immunosuppressed patients

**Authority required (STREAMLINED)**

3614

Treatment of oesophageal candidiasis in immunosuppressed patients

**Authority required (STREAMLINED)**

3617

Prophylaxis of oropharyngeal candidiasis in immunosuppressed patients

**Authority required (STREAMLINED)**

3618

Treatment of serious and life-threatening candida infections

**Note**

Shared Care Model:

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

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## ANTIINFECTIVES FOR SYSTEMIC USE

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<td>a Dizole 100, a Fluconazole Sandoz, a Ozole, a Diflucan, a Fluconazole-Claris, a Fluconazole Hexal, a Fluconazole Sandoz, a APO-Fluconazole</td>
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### FLUCONAZOLE

**Authority required**

Treatment of cryptococcal meningitis in a patient unable to take a solid dose form of fluconazole

**Authority required**

Maintenance therapy in a patient with cryptococcal meningitis and immunosuppression unable to take a solid dose form of fluconazole

**Authority required**

Treatment of oropharyngeal candidiasis in an immunosuppressed patient unable to take a solid dose form of fluconazole

**Authority required**

Treatment of oesophageal candidiasis in an immunosuppressed patient unable to take a solid dose form of fluconazole

**Authority required**

Prophylaxis of oropharyngeal candidiasis in an immunosuppressed patient unable to take a solid dose form of fluconazole

**Authority required**

Treatment of serious and life-threatening candida infections in a patient unable to take a solid dose form of fluconazole

**Note**

Additional care model:

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

### ITRACONAZOLE

**Authority required (STREAMLINED)**

3607  
Systemic aspergillosis

**Authority required (STREAMLINED)**

3608  
Systemic sporotrichosis

**Authority required (STREAMLINED)**

3609  
Systemic histoplasmosis

**Authority required (STREAMLINED)**

3610
Treatment and maintenance therapy in patients with AIDS who have disseminated pulmonary histoplasmosis infection

**Authority required (STREAMLINED)**

3612

Treatmen and maintenance therapy in patients with AIDS who have chronic pulmonary histoplasmosis infection

**Authority required (STREAMLINED)**

3613

Treatment of oropharyngeal candidiasis in immunosuppressed patients

**Authority required (STREAMLINED)**

3614

Treatment of oesophageal candidiasis in immunosuppressed patients

**Note**

Shared Care Model:

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

8196J

NP

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POSACONAZOLE

**Authority required**

Treatment of invasive aspergillosis in patients intolerant to, or with disease refractory to, alternative therapy

**Authority required**

Treatment of fusariosis, zygomycosis, coccidioidomycosis, chromoblastomycosis and mycetoma in patients intolerant to, or with disease refractory to, alternative therapy

**Authority required**

Prophylaxis of invasive fungal infections, including both yeasts and moulds, in a patient who is at high risk of developing these infections, defined as follows:

1. Neutropenia
   - Patients with anticipated neutropenia (an absolute neutrophil count of less than 500 cells per cubic millimetre) for at least 10 days, who are receiving chemotherapy for acute myelogenous leukaemia or myelodysplastic syndrome.
   - Treatment should continue until recovery of the neutrophil count to at least 500 cells per cubic millimetre.
2. Graft versus host disease (GVHD)
   - Patients who have had a previous invasive fungal infection should have secondary prophylaxis during subsequent episodes of neutropenia.
   - Patients with acute GVHD grades II to IV or extensive chronic GVHD, who are receiving intensive immunosuppressive therapy after allogeneic haematopoietic stem cell transplant.
   - No more than 6 months therapy per episode will be PBS-subsidised

**Note**

Application for an increased maximum quantity to allow for up to 1 month’s treatment and repeats sufficient for up to 6 months’ treatment may be authorised.

**Note**

Shared Care Model:

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

9360P

NP

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<td>posaconazole 40 mg/mL oral liquid, 105 mL</td>
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<td>733.60</td>
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VORICONAZOLE

**Authority required**

For the treatment and maintenance therapy of definite or probable invasive aspergillosis in immunocompromised patients

**Authority required**

For the treatment and maintenance therapy of serious fungal infections caused by Scedosporium species or Fusarium species

**Authority required**

For the treatment and maintenance therapy of serious Candida infections where the causative species is not susceptible to fluconazole

**Authority required**

For the treatment and maintenance therapy of serious Candida infections where treatment with fluconazole has failed

**Authority required**

For the treatment and maintenance therapy of serious Candida infections where treatment with fluconazole is not tolerated

**Authority required**

For the treatment and maintenance therapy of other serious invasive mycosis
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**VORICONAZOLE**

**Authority required**
For the treatment and maintenance therapy of definite or probable invasive aspergillosis in immunocompromised patients

**Authority required**
For the treatment and maintenance therapy of serious fungal infections caused by Scedosporium species or Fusarium species

**Authority required**
For the treatment and maintenance therapy of serious Candida infections where the causative species is not susceptible to fluconazole

**Authority required**
For the treatment and maintenance therapy of serious Candida infections where treatment with fluconazole has failed

**Authority required**
For the treatment and maintenance therapy of serious Candida infections where treatment with fluconazole is not tolerated

**Authority required**
For the treatment and maintenance therapy of other serious invasive mycosis

**Note**
Application for an increased maximum quantity to allow for up to 1 month’s treatment and repeats sufficient for up to 6 months’ treatment may be authorised.

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

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**ANTIMYCOBACTERIALS**

**DRUGS FOR TREATMENT OF TUBERCULOSIS**

**Hydrazides**

**ISONIAZID**

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

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**DRUGS FOR TREATMENT OF LEPRO**

**Drugs for treatment of lepra**

**DAPSONE**

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

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<td>8801F</td>
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**RIFAMPICIN**

**Restricted benefit**
Prophylaxis of meningococcal disease in close contacts and carriers

**Restricted benefit**

**Shared Care Model:**
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.
### ANTIINFECTIVES FOR SYSTEMIC USE

#### RIFAMPICIN

**Authority required**

Leprosy in adults

**Note**

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

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<td>1981G</td>
<td>rifampicin 150 mg capsule, 10</td>
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<td>Rimycin 150 AF</td>
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<td>1984K</td>
<td>rifampicin 300 mg capsule, 10</td>
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### ANTIVIRALS FOR SYSTEMIC USE

#### DIRECT ACTING ANTIVIRALS

**Nucleosides and nucleotides excl. reverse transcriptase inhibitors**

**ACICLOVIR**

**Authority required (STREAMLINED)**

3632

Moderate to severe initial genital herpes. Microbiological confirmation of diagnosis (viral culture, antigen detection or nucleic acid amplification by PCR) is desirable but need not delay treatment

**Note**

Aciclovir 200 mg is not PBS-subsidised for chickenpox, herpes zoster or herpes simplex infections other than genital herpes.

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

**Note**

For item codes 1003T and 1555W, pharmaceutical benefits that have the form tablet 200 mg are equivalent for the purposes of substitution.

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**ACICLOVIR**

**Authority required (STREAMLINED)**

3633

Episodic treatment or suppressive therapy of moderate to severe recurrent genital herpes. Microbiological confirmation of diagnosis (viral culture, antigen detection or nucleic acid amplification by PCR) is required but need not delay treatment

**Note**

Aciclovir 200 mg is not PBS-subsidised for chickenpox, herpes zoster or herpes simplex infections other than genital herpes.

<table>
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<tr>
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<td>Patients with advanced HIV disease (CD4 cell counts of less than 150 million per litre)</td>
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<tr>
<td>3622</td>
<td>Treatment of patients with herpes zoster within 72 hours of the onset of the rash</td>
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<td>Aciclovir is effective only if commenced within 72 hours of onset of rash.</td>
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<td>Aciclovir 800 mg is not PBS-subsidised for herpes simplex or chickenpox.</td>
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<td>No applications for repeats will be authorised.</td>
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<td>3624</td>
<td>Episodic treatment of moderate to severe recurrent genital herpes. Microbiological confirmation of diagnosis (viral culture, antigen detection or nucleic acid amplification by PCR) is required but need not delay treatment</td>
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<td></td>
<td>Famiciclovir 125 mg is not PBS-subsidised for chickenpox, herpes zoster or herpes simplex infections other than genital herpes.</td>
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<tr>
<td></td>
<td>Famiciclovir 250 mg is not PBS-subsidised for chickenpox or herpes simplex infections other than genital herpes.</td>
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</table>
### Authority required (STREAMLINED)

#### 3622

Treatment of patients with herpes zoster within 72 hours of the onset of the rash

**Note**

Famciclovir is effective only if commenced within 72 hours of onset of rash.

Famciclovir 250 mg is not PBS-subsidised for chickenpox or herpes simplex infections other than genital herpes.

**Note**

No applications for repeats will be authorised.

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
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### FAMCICLOVIR

#### Authority required (STREAMLINED)

#### 3623

Suppressive therapy of moderate to severe recurrent genital herpes. Microbiological confirmation of diagnosis (viral culture, antigen detection or nucleic acid amplification by PCR) is required but need not delay treatment

**Note**

Famciclovir 250 mg is not PBS-subsidised for chickenpox or herpes simplex infections other than genital herpes.

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<th>Code</th>
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### FAMCICLOVIR

#### Authority required (STREAMLINED)

#### 3625

Treatment of immunocompromised patients with herpes zoster within 72 hours of the onset of the rash

**Note**

Famciclovir is effective only if commenced within 72 hours of onset of rash.

Famciclovir 500 mg is not PBS-subsidised for chickenpox.

Famciclovir 500 mg is not PBS-subsidised for herpes zoster, genital herpes or other herpes simplex infections in immunocompetent patients.

**Note**

No applications for repeats will be authorised.

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</table>
## FAMCICLOVIR

**Authority required (STREAMLINED)**

3626

Episodic treatment or suppressive therapy of moderate to severe recurrent genital herpes in immunocompromised patients. Microbiological confirmation of diagnosis (viral culture, antigen detection or nucleic acid amplification by PCR) is required but need not delay treatment.

**Authority required (STREAMLINED)**

3627

Episodic treatment of moderate to severe recurrent oral or labial herpes in a patient with HIV infection and a CD4 cell count of less than 500 million per litre. Microbiological confirmation of diagnosis (viral culture, antigen detection or nucleic acid amplification by PCR) is required but need not delay treatment.

**Authority required (STREAMLINED)**

3628

Suppressive therapy of moderate to severe recurrent oral or labial herpes in a patient with HIV infection and a CD4 cell count of less than 150 million per litre. Microbiological confirmation of diagnosis (viral culture, antigen detection or nucleic acid amplification by PCR) is required but need not delay treatment.

**Authority required (STREAMLINED)**

3629

Suppressive therapy of moderate to severe recurrent oral or labial herpes in a patient with HIV infection and other opportunistic infections or AIDS defining tumours. Microbiological confirmation of diagnosis (viral culture, antigen detection or nucleic acid amplification by PCR) is required but need not delay treatment.

**Note**

Famciclovir 500 mg is not PBS-subsidised for chickenpox.

Famciclovir 500 mg is not PBS-subsidised for herpes zoster, genital herpes or other herpes simplex infections in immunocompetent patients.

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## VALACICLOVIR

**Authority required (STREAMLINED)**

3632

Moderate to severe initial genital herpes. Microbiological confirmation of diagnosis (viral culture, antigen detection or nucleic acid amplification by PCR) is desirable but need not delay treatment.

**Note**

Valaciclovir 500 mg is not PBS-subsidised for chickenpox or herpes simplex infections other than genital herpes.

**Note**

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

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## VALACICLOVIR

**Authority required (STREAMLINED)**
### Antiinfectives for Systemic Use

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**Note**

Valaciclovir 500 mg is not PBS-subsidised for chickenpox or herpes simplex infections other than genital herpes.
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**VACCINES**

**BACTERIAL VACCINES**

*Pneumococcal vaccines*

**PNEUMOCOCCAL PURIFIED CAPSULAR POLYSACCHARIDES**

*Restricted benefit*

- Splenectomised persons over 2 years of age
- Persons with Hodgkin’s disease
- Persons at high risk of pneumococcal infections

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<td>1903E</td>
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<td>47.96</td>
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**Tetanus vaccines**

**DIPHTHERIA TOXOID + TETANUS TOXOID**

*Note*

For immunisation of adults and children aged greater than or equal to 8 years.

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<td>8783G</td>
<td>diphtheria toxoid 2 international units/0.5 mL + tetanus toxoid 20 international units/0.5 mL injection, 5 x 0.5 mL syringes</td>
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### ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

**ANTINEOPLASTIC AGENTS**

**ALKYLATING AGENTS**

**Nitrogen mustard analogues**

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**Alkyl sulfonates**

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<td>96.18</td>
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**Nitrosoureas**

**CARMUSTINE**

Restricted benefit

Glioblastoma multiforme, suspected or confirmed, at the time of initial surgery

*Note*

Carmustine is not PBS-subsidised for use in conjunction with PBS-subsidised temozolomide.

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**Other alkylating agents**

**TEMOZOLOMIDE**

Authority required

Recurrence of anaplastic astrocytoma following standard therapy

Authority required

Recurrence of glioblastoma multiforme following standard therapy

Authority required

Glioblastoma multiforme following radiotherapy

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**ANTIMETABOLITES**

**Folic acid analogues**

**METHOTREXATE**

**Note**
For item codes 2395C and 1818Q, pharmaceutical benefits that have the form injection 50 mg in 2 mL are equivalent for the purposes of substitution.

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**Purine analogues**

**FLUDARABINE**

**Authority required**
B-cell chronic lymphocytic leukaemia in combination with cyclophosphamide where the patient has advanced disease (Binet Stage B or C) or evidence of progressive Stage A disease.

Stage A progressive disease is defined by at least one of the following: persistent rise in lymphocyte count with doubling time less than 12 months; a downward trend in haemoglobin or platelets, or both; more than 50% increase in the size of liver, spleen, or lymph nodes, or appearance of these signs if not previously present; constitutional symptoms attributable to disease.

The diagnosis of chronic lymphocytic leukaemia (CLL) must have been established based on:
(a) a lymphocytosis, with more than 5,000 million lymphocytes per L in the peripheral blood; and
(b) a clonal population of B-cells (CD5/CD19) documented by flow cytometry

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**Pyrimidine analogues**

**CAPECITABINE**

**Authority required**
Advanced breast cancer after failure of prior therapy which includes a taxane and an anthracycline
ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

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**Authority required**

Advanced breast cancer where therapy with a taxane and/or an anthracycline is contraindicated

**Authority required**

Advanced breast cancer in combination with docetaxel after failure of prior anthracycline-containing chemotherapy

**Authority required**

Treatment of advanced or metastatic colorectal cancer

**Authority required**

Adjuvant treatment of stage III (Dukes C) colon cancer, following complete resection of the primary tumour either as:
(a) monotherapy; or
(b) in combination with oxaliplatin

**Authority required**

Advanced (Stage III or IV) oesophago-gastric cancer, previously untreated, in combination with a cisplatin-based regimen, in a patient with a WHO performance status of 2 or less

**Note**

In the adjuvant setting, the recommended treatment duration is 24 weeks.

Capecitabine is not PBS-subsidised for the treatment of patients with stage II (Dukes B) colon cancer.

Capecitabine is not PBS-subsidised for the adjuvant treatment of patients with rectal cancer.

8361C capecitabine 150 mg tablet, 60 1 2 .. 105.47 36.90

8362D capecitabine 500 mg tablet, 120 1 2 .. 585.31 36.90

---

PLANT ALKALOIDS AND OTHER NATURAL PRODUCTS

*Vinca alkaloids and analogues*

**VINORELBINE**

**Authority required**

Advanced breast cancer

**Clinical criteria:**

Patient must have failed standard prior therapy, which includes an anthracycline.

**Authority required**

Locally advanced or metastatic non-small cell lung cancer

9009E vinorelbine 20 mg capsule, 1 20 2 .. *1579.56 36.90 Navelbine FB

9010F vinorelbine 30 mg capsule, 1 16 2 .. *1887.56 36.90 Navelbine FB

**Podophyllotoxin derivatives**

**ETOPOSIDE**

1389D etoposide 100 mg capsule, 10 1 .. .. 391.07 36.90 Vepesid BQ

1396L etoposide 50 mg capsule, 20 1 .. .. 445.28 36.90 Vepesid BQ

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CYTOTOXIC ANTIBIOTICS AND RELATED SUBSTANCES

*Anthracyclines and related substances*

**IDARUBICIN**

Restricted benefit
### ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

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#### OTHER ANTINEOPLASTIC AGENTS

**Protein kinase inhibitors**

**DABRAFENIB**

**Authority required**

Unresectable Stage III or Stage IV malignant melanoma

Treatment Phase: Continuing treatment

**Clinical criteria:**

The treatment must be the sole PBS-subsidised therapy for this condition,

AND

Patient must have previously been issued with an authority prescription for this drug,

AND

Patient must have stable or responding disease.

**Note**

A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.

**Note**

A patient who has had progressive disease when treated with another BRAF inhibitor is not eligible to receive PBS-subsidised treatment with this drug.

**Note**

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

**Note**

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

**Note**

Special Pricing Arrangements apply.

2954L dabrafenib 50 mg capsule, 120 1 5 .. 5888.15 36.90 Tafinlar GK

10003L dabrafenib 75 mg capsule, 120 1 5 .. 8758.87 36.90 Tafinlar GK

**DABRAFENIB**

**Authority required**

Unresectable Stage III or Stage IV malignant melanoma

Treatment Phase: Initial treatment

**Clinical criteria:**

The treatment must be the sole PBS-subsidised therapy for this condition,

AND

The condition must be positive for a BRAF V600 mutation,

AND

The condition must not have been treated previously with PBS subsidised therapy; OR

Patient must have developed intolerance to another BRAF inhibitor of a severity necessitating permanent treatment withdrawal,

AND

Patient must have a WHO performance status of 2 or less.

**Note**

A patient who has had progressive disease when treated with another BRAF inhibitor is not eligible to receive PBS-subsidised treatment with this drug.
### ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

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

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

**Note**
Special Pricing Arrangements apply.

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### DASATINIB

**Authority required**
Initial treatment, as the sole PBS-subsidised therapy, of a patient in the chronic phase of chronic myeloid leukaemia expressing the Philadelphia chromosome or the transcript, BCR-ABL tyrosine kinase, and who has a primary diagnosis of chronic myeloid leukaemia.

Applications under this restriction will be limited to provide patients with a maximum of 18 months of therapy with dasatinib, imatinib or nilotinib from the date the first application for initial treatment was approved.

Patients should be commenced on a dose of dasatinib of at least 100 mg (base) daily. Continuing therapy is dependent on patients demonstrating a response to dasatinib therapy following the initial 18 months of treatment and at 12 monthly intervals thereafter.

Applications for authorisation must be in writing and must include:

1. a completed authority prescription form; and
2. a completed Chronic Myeloid Leukaemia - Chronic Phase, First Line - Supporting Information form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and
3. a pathology cytogenetic report conducted on peripheral blood or bone marrow supporting the diagnosis of chronic myeloid leukaemia to confirm eligibility for treatment, or a qualitative PCR report documenting the presence of the BCR-ABL transcript in either peripheral blood or bone marrow; and
4. a signed patient acknowledgement form

**Authority required**
Continuing treatment, as the sole PBS-subsidised therapy, of a patient who has received initial PBS-subsidised treatment with dasatinib for the chronic phase of chronic myeloid leukaemia and who has demonstrated either a major cytogenetic response or less than 1% BCR-ABL level in the blood.

Applications for authorisation must be in writing and must include:

1. a completed authority prescription form; and
2. demonstration of continued response to treatment as evidenced by either:
   a. major cytogenetic response [see Note explaining requirements]. Where this has been supplied within the previous 12 months, only the date of the relevant pathology report need be provided; or
   b. a peripheral blood level of BCR-ABL of less than 1% on the international scale [see Note explaining requirements]. Where this has been supplied within the previous 12 months, only the date of the relevant pathology report need be provided

**Note**
Any queries concerning the arrangements to prescribe dasatinib may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Applications for authority to prescribe dasatinib should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

**Note**
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of tyrosine kinase inhibitors (TKI) agents for the chronic phase of chronic myeloid leukaemia. Where the term TKI agent appears in the following notes and restrictions it refers to imatinib mesylate, dasatinib or nilotinib.

Patients are eligible for PBS-subsidised treatment with only one TKI agent at any one time and must not be receiving concomitant interferon alfa therapy. Eligible patients may only swap between TKI agents if they have not failed prior PBS-subsidised treatment with that agent.

1. Initial treatment - Imatinib mesylate, dasatinib and nilotinib

From 1 April 2012, under the PBS, a patient will be able to be prescribed any of imatinib mesylate, dasatinib or nilotinib within the initial 18 month treatment period, as long as only one agent is used at a time and providing the patient has not failed to respond to any one of these TKIs.
During the initial 18 month treatment period, switching between approved first-line agents may only occur for reasons of intolerance, not failure of response.

2. Continuing treatment with imatinib mesylate - first-line

First continuing applications are to be written and must include a pathology report demonstrating the patient has responded to the initial course of treatment.

Second and subsequent authority applications for continuing therapy with imatinib mesylate may be made on the telephone by contacting Medicare Australia on 1800 700 720 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Patients must maintain a major cytogenetic response or have a peripheral blood BCR-ABL of less than 1% to receive continuing therapy.

3. Continuing treatment with dasatinib or nilotinib - first-line

All continuing applications are to be written and must include a pathology report demonstrating the patient has responded to PBS-subsidised treatment as follows:

(i) within 18 months of the commencement of treatment, at which time patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% has been demonstrated may receive authorisation for a further 12 months of treatment; and

(ii) at no greater than 12 month intervals thereafter, to demonstrate that the major cytogenetic response or peripheral blood BCR-ABL level of less than 1% has been sustained.

4. For imatinib mesylate, dasatinib and nilotinib

During continuing therapy beyond the initial 18 month treatment period, switching between approved first-line agents may only occur for reason of intolerance. Where there is failure of response, switching may only occur through application for prescription of second-line agents.

Where a patient has previously received PBS-subsidised treatment with imatinib mesylate, dasatinib or nilotinib no approval will be granted for PBS-subsidised re-treatment in the chronic phase of chronic myeloid leukaemia, where that patient has at any time failed to meet the response criteria whilst on that TKI agent.

5. Authority approval requirements.

Response criteria to initial treatment with imatinib mesylate, dasatinib or nilotinib:

For the purposes of assessing response to PBS-subsidised treatment with imatinib mesylate, dasatinib or nilotinib either cytogenetic analysis indicating the number of Philadelphia positive \([t (9;22)]\) cells in the bone marrow measured by standard karyotyping, or quantitative PCR indicating the relative level of BCR-ABL transcript in the peripheral blood using the international scale, must be submitted. For bone marrow analyses, where the relative level of BCR-ABL in the bone marrow measured by standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe must be submitted. The cytogenetic or peripheral blood quantitative PCR analyses must be submitted within 18 months of the commencement of treatment with imatinib mesylate, dasatinib or nilotinib (patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% is demonstrable by 18 months are eligible to receive continuing treatment with that agent).


A major cytogenetic response is defined as less than 35% Philadelphia positive bone marrow cells.

A peripheral blood BCR-ABL level of less than 1% on the international scale (Blood 108: 28-37, 2006) also indicates a response, at least the biological equivalent of a major cytogenetic response.

7. Definitions of loss of response.

Loss of a previously documented major cytogenetic response (defined by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing tyrosine kinase inhibitor (TKI) therapy.

Loss of a previously demonstrated molecular response (defined by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing tyrosine kinase inhibitor therapy.

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**DASATINIB**

**Authority required**

Initial treatment, as the sole PBS-subsidised therapy, of a patient with chronic myeloid leukaemia in any disease phase who has failed an adequate trial of imatinib or nilotinib as first-line treatment.

Failure of an adequate trial of imatinib or nilotinib is defined as:

(i) Lack of response to initial imatinib or nilotinib therapy, defined as either:

— failure to achieve a haematological response after a minimum of 3 months therapy with imatinib or nilotinib for patients initially treated in chronic phase; or

— failure to achieve any cytogenetic response after a minimum of 6 months therapy with imatinib or nilotinib for patients initially treated in chronic phase as demonstrated on bone marrow biopsy by presence of greater than 95% Philadelphia chromosome positive cells; or
— failure to achieve a major cytogenetic response or a peripheral blood BCR-ABL level of less than 1% after a minimum of 12 months therapy with imatinib or nilotinib; OR

(ii) Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing imatinib or nilotinib therapy; OR

(iii) Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing imatinib or nilotinib therapy; OR

(iv) Development of accelerated phase or blast crisis in a patient previously prescribed imatinib or nilotinib for any phase of chronic myeloid leukaemia.

Accelerated phase is defined by the presence of 1 or more of the following:

(1) Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 15% but less than 30%; or

(2) Percentage of blasts plus promyelocytes in the peripheral blood or bone marrow greater than or equal to 30%, provided that blast count is less than 30%; or

(3) Peripheral basophils greater than or equal to 20%; or

(4) Progressive splenomegaly to a size greater than or equal to 10 cm below the left costal margin to be confirmed on 2 occasions at least 4 weeks apart, or a greater than or equal to 50% increase in size below the left costal margin over 4 weeks; or

(5) Karyotypic evolution (chromosomal abnormalities in addition to a single Philadelphia chromosome); OR

Blast crisis is defined as either:

(1) Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 30%; or

(2) Extramedullary involvement other than spleen and liver; OR

(v) Disease progression (defined as a greater than or equal to 50% increase in peripheral white blood cell count, blast count, basophils or platelets) during first-line imatinib or nilotinib therapy in patients with accelerated phase or blast crisis chronic myeloid leukaemia.

Patients should be commenced on a dose of dasatinib of at least 100 mg (base) daily. Continuing therapy is dependent on patients demonstrating a major cytogenetic response to dasatinib therapy or a peripheral blood BCR-ABL level of less than 1% within 18 months and thereafter at 12 monthly intervals.

Applications for authorisation must be in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Chronic Myeloid Leukaemia - Second and Third Line - Supporting Information Form; and

(c) a signed patient acknowledgement; and

(d) a bone marrow biopsy pathology report demonstrating the patient has active chronic myeloid leukaemia, either manifest as cytogenetic evidence of the Philadelphia chromosome, or RT-PCR level of BCR-ABL transcript greater than 0.1% on the international scale. (The date of the relevant pathology report needs to be provided); and

(e) where there has been a loss of response to imatinib or nilotinib, a copy of the current confirming pathology report(s) from an Approved Pathology Authority or details of the dates of assessment in the case of progressive splenomegaly or extramedullary involvement

**Authority required**

Continuing treatment, as the sole PBS-subsidised therapy, of a patient who has received initial PBS-subsidised treatment with dasatinib for chronic myeloid leukaemia, and who has demonstrated either a major cytogenetic response, or less than 1% BCR-ABL level in the blood, to dasatinib in the preceding 18 months and thereafter at 12 monthly intervals.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Chronic Myeloid Leukaemia - Second and Third Line - Application Form for continuing treatment; and

(3) demonstration of continued response to treatment as evidenced by either:

(a) major cytogenetic response [see Note explaining definitions of response]. Where this has been supplied within the previous 12 months (or 18 months for the initial supply), the only date of the relevant pathology report needs to be provided; or

(b) a peripheral blood level of BCR-ABL of less than 1% on the international scale [see Note explaining definitions of response]. Where this has been supplied within the previous 12 months (or 18 months for the initial supply), only the date of the relevant pathology report needs to be provided

**Note**

Any queries concerning the arrangements to prescribe dasatinib may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Applications for authority to prescribe dasatinib should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001
From 1 April 2012, under the PBS, a patient will be able to be prescribed either dasatinib or nilotinib within the initial 18 month treatment period as second-line therapy, as long as only one agent is approved at a time and providing the patient did not fail that drug as first-line therapy.

During the initial 18 month treatment period, switching between approved second-line agents may only occur for reasons of intolerance, not failure of response.

2. Initial third line treatment

Third-line treatment with a TKI can only be approved when imatinib is used for first-line treatment. Patients will only be approved for PBS-subsidised treatment with one third-line agent.

From 1 April 2012, under the PBS, a patient will be able to be prescribed either dasatinib or nilotinib providing the patient did not fail that drug as first or second line therapy and for nilotinib the patient is not in blast crisis.

3. Continuing treatment for second and third line treatment

All continuing applications are to be written and must include a pathology report demonstrating the patient has responded to PBS-subsidised treatment as follows:

(i) within 18 months of the commencement of treatment, at which time patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% has been demonstrated may receive authorisation for a further 12 months of treatment; and

(ii) at no greater than 12 month intervals thereafter, to demonstrate that the major cytogenetic response or peripheral blood BCR-ABL level of less than 1% has been sustained.

During second line continuing treatment beyond the initial 18 month treatment period, switching between approved second line TKI agents may only occur for reason of intolerance. Where there is failure of response, switching may only occur through application for prescription of a third line agent.

4. Authority approval requirements.

Response criteria to initial treatment with dasatinib or nilotinib:

For the purposes of assessing response to PBS-subsidised treatment with dasatinib or nilotinib, either cytogenetic analysis indicating the number of Philadelphia positive [t (9:22)] cells in the bone marrow measured by standard karyotyping, or quantitative PCR indicating the relative level of BCR-ABL transcript in the peripheral blood using the international scale, must be submitted. For bone marrow analyses, where the standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe must be submitted. The cytogenetic or peripheral blood quantitative PCR analyses must be submitted within 18 months of the commencement of treatment with dasatinib or nilotinib (patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% is demonstrable by 18 months are eligible to receive continuing treatment with that agent).

5. Definitions of response.

A major cytogenetic response is defined as less than 35% Philadelphia positive bone marrow cells.

A peripheral blood BCR-ABL level of less than 1% on the international scale (Blood 108: 28-37, 2006) also indicates a response, at least the biological equivalent of a major cytogenetic response.


Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing tyrosine kinase inhibitor (TKI) therapy.

Loss of a previously documented molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing tyrosine kinase inhibitor therapy.
transplantation.

Failure of treatment is defined as either:

(i) Failure to achieve a complete morphological and cytogenetic remission after a minimum of 2 months treatment with intensive chemotherapy and imatinib;

(ii) Morphological or cytogenetic relapse of leukaemia after achieving a complete remission induced by chemotherapy and imatinib;

(iii) Morphological or cytogenetic relapse or persistence of leukaemia after allogeneic haemopoietic stem cell transplantation.

Patients must have active leukaemia, as defined by presence on current pathology assessments of either morphological infiltration of the bone marrow (greater than 5% lymphoblasts) or cerebrospinal fluid or other sites; OR the presence of cells bearing the Philadelphia chromosome on cytogenetic or FISH analysis in the bone marrow of patients in morphological remission.

The first authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Acute Lymphoblastic Leukaemia Dasatinib PBS Authority Application - Supporting Information Form; and

(c) a signed patient acknowledgement; and

(d) a pathology report demonstrating that the patient has active acute lymphoblastic leukaemia, either manifest as cytogenetic evidence of the Philadelphia chromosome, or morphological evidence of acute lymphoblastic leukaemia plus qualitative RT-PCR evidence of BCR-ABL transcript. The date of the relevant pathology report(s) need(s) to be provided.

Authority required

Initial treatment, as monotherapy, of a patient with acute lymphoblastic leukaemia bearing the Philadelphia chromosome or expressing the transcript, BCR-ABL, who has been treated prior to 1 December 2007; and has failed treatment with chemotherapy and where appropriate, allogeneic haemopoietic stem cell transplantation.

Patients must have active leukaemia, as defined by presence on current pathology assessments of either morphological infiltration of the bone marrow (greater than 5% lymphoblasts) or cerebrospinal fluid or other sites; OR the presence of cells bearing the Philadelphia chromosome on cytogenetic or FISH analysis in the bone marrow of patients in morphological remission.

The first authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Acute Lymphoblastic Leukaemia Dasatinib PBS Authority Application - Supporting Information Form; and

(c) a signed patient acknowledgement; and

(d) a pathology report demonstrating that the patient has active acute lymphoblastic leukaemia, either manifest as cytogenetic evidence of the Philadelphia chromosome, or morphological evidence of acute lymphoblastic leukaemia plus qualitative RT-PCR evidence of BCR-ABL transcript. The date of the relevant pathology report(s) need(s) to be provided.

Authority required

Continuing treatment, as monotherapy, of a patient with acute lymphoblastic leukaemia bearing the Philadelphia chromosome or expressing the transcript, BCR-ABL, where the patient has previously been issued with an authority prescription for dasatinib and does not have progressive disease.

Authority applications for continuing treatment may be made by telephone on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Note

Any queries concerning the arrangements to prescribe dasatinib may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Applications for authority to prescribe dasatinib should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

Note

Dasatinib will only be subsidised for patients with acute lymphoblastic leukaemia who are not receiving concomitant PBS-subsidised imatinib mesylate and who are not appropriate for an allogeneic haemopoietic stem cell transplant.

Note

No applications for increased repeats will be authorised.

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**ERLOTINIB**

**Authority required**
Stage III B (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)

**Clinical criteria:**
The treatment must be as monotherapy, AND
Patient must have previously been issued with an authority prescription for this drug prior to 1 August 2014, AND
Patient must not have progressive disease.

**Population criteria:**
Patient must have a wild type epidermal growth factor receptor (EGFR) gene; OR
Patient must have an epidermal growth factor receptor (EGFR) gene of unknown type.

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**ERLOTINIB**

**Authority required**
Stage III B (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)

**Clinical criteria:**
The treatment must be as monotherapy, AND
The condition must be non-squamous type non-small cell lung cancer (NSCLC) or not otherwise specified type NSCLC, AND
Patient must not have received previous PBS-subsidised treatment with another epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor (TKI); OR
Patient must have developed intolerance to another epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor (TKI) of a severity necessitating permanent treatment withdrawal, AND
Patient must have a WHO performance status of 2 or less.

**Population criteria:**
Patient must have evidence of an activating epidermal growth factor receptor (EGFR) gene mutation known to confer sensitivity to treatment with EGFR tyrosine kinase inhibitors in tumour material.

**Authority required**
Stage III B (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)

**Clinical criteria:**
The treatment must be as monotherapy, AND
Patient must have previously been issued with an authority prescription for this drug, AND
Patient must not have progressive disease.

**Population criteria:**
Patient must have evidence of an activating epidermal growth factor receptor (EGFR) gene mutation known to confer sensitivity to treatment with EGFR tyrosine kinase inhibitors in tumour material.
### EVEROLIMUS

#### Authority required

Stage IV clear cell variant renal cell carcinoma (RCC)

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have progressive disease according to the Response Evaluation Criteria In Solid Tumours (RECIST) following first-line treatment with a tyrosine kinase inhibitor,

  **AND**

- Patient must have a WHO performance status of 2 or less,

  **AND**

- The treatment must be the sole PBS-subsidised therapy for this condition.

Patients who have developed intolerance to a tyrosine kinase inhibitor of a severity necessitating permanent treatment withdrawal are eligible to receive PBS-subsidised everolimus.

Patients who have progressive disease with everolimus are no longer eligible for PBS-subsidised everolimus.

**Note**

Response Evaluation Criteria In Solid Tumours (RECIST) is defined as follows:

- Complete response (CR) is disappearance of all target lesions.
- Partial response (PR) is a 30% decrease in the sum of the longest diameter of target lesions.
- Progressive disease (PD) is a 20% increase in the sum of the longest diameter of target lesions.
- Stable disease (SD) is small changes that do not meet above criteria.

**Note**

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

**Note**

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

**Note**

Special Pricing Arrangements apply.

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### EVEROLIMUS

#### Authority required

Stage IV clear cell variant renal cell carcinoma (RCC)

Treatment Phase: Continuing treatment beyond 3 months

**Clinical criteria:**

- Patient must have previously been issued with an authority prescription for this drug for this condition,

  **AND**

- Patient must have stable or responding disease according to the Response Evaluation Criteria In Solid Tumours (RECIST),

  **AND**

- The treatment must be the sole PBS-subsidised therapy for this condition.

Patients who have progressive disease with everolimus are no longer eligible for PBS-subsidised everolimus.

**Note**

Response Evaluation Criteria In Solid Tumours (RECIST) is defined as follows:

- Complete response (CR) is disappearance of all target lesions.
- Partial response (PR) is a 30% decrease in the sum of the longest diameter of target lesions.
- Progressive disease (PD) is a 20% increase in the sum of the longest diameter of target lesions.
- Stable disease (SD) is small changes that do not meet above criteria.

**Note**

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

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EVEROLIMUS

**Authority required**

Tuberous sclerosis complex (TSC)

Treatment Phase: Initial treatment

**Clinical criteria:**

The condition must be subependymal giant cell astrocytomas (SEGAs) associated with TSC; OR

The condition must be visceral tumours associated with TSC,

AND

The treatment must be the sole PBS-subsidised therapy for this condition,

AND

Patient must not be a candidate for curative surgical resection.

**Note**

Special Pricing Arrangements apply.

**Authority required**

Tuberous sclerosis complex (TSC)

Treatment Phase: Continuing treatment

**Clinical criteria:**

The condition must be subependymal giant cell astrocytomas (SEGAs) associated with TSC; OR

The condition must be visceral tumours associated with TSC,

AND

The treatment must be the sole PBS-subsidised therapy for this condition,

AND

Patient must have previously been treated with PBS-subsidised everolimus for this condition,

AND

Patient must have demonstrated a response to prior treatment.

**Note**

Special Pricing Arrangements apply.

**Authority required**

Metastatic (Stage IV) breast cancer

**Clinical criteria:**

The condition must be hormone receptor positive,

AND

The condition must be human epidermal growth factor receptor 2 (HER2) negative,

AND

The condition must have acquired endocrine resistance as demonstrated by initial response and then recurrence or progression of disease after treatment with letrozole or anastrozole,

AND

The treatment must be in combination with exemestane.

**Population criteria:**

Patient must be female,

AND

Patient must be post-menopausal.

**Note**

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

Special Pricing Arrangements apply.

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Patients who have progressive disease with everolimus are no longer eligible for PBS-subsidised everolimus.

### EVEROLIMUS

**Authority required**
- Tuberous sclerosis complex (TSC)

**Treatment Phase: Initial treatment**

**Clinical criteria:**
- The condition must be subependymal giant cell astrocytomas (SEGAs) associated with TSC; OR
- The condition must be visceral tumours associated with TSC,
- **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition,
- **AND**
- Patient must not be a candidate for curative surgical resection.

### EVEROLIMUS

**Authority required**
- Tuberous sclerosis complex (TSC)

**Treatment Phase: Continuing treatment**

**Clinical criteria:**
- The condition must be subependymal giant cell astrocytomas (SEGAs) associated with TSC; OR
- The condition must be visceral tumours associated with TSC,
- **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition,
- **AND**
- Patient must have previously been treated with PBS-subsidised everolimus for this condition,
- **AND**
- Patient must have demonstrated a response to prior treatment.

Note: Special Pricing Arrangements apply.

#### 2985D
- **everolimus 10 mg tablet, 30**
- Max. Qty (Packs): 1
- No. of Rpts: 5
- Dispensed Price for Max. Qty $: 5546.70
- Premium $: 36.90
- Brand Name and Manufacturer: Afinitor NV

#### 2819J
- **everolimus 5 mg tablet, 30**
- Max. Qty (Packs): 1
- No. of Rpts: 5
- Dispensed Price for Max. Qty $: 2846.70
- Premium $: 36.90
- Brand Name and Manufacturer: Afinitor NV

### GEFitinib

**Authority required**
- Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)

**Treatment Phase: Initial treatment**

**Clinical criteria:**
- The treatment must be as monotherapy,
- **AND**
- The condition must be non-squamous type non-small cell lung cancer (NSCLC) or not otherwise specified type NSCLC,
- **AND**
- Patient must not have received previous PBS-subsidised treatment with another epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor (TKI); OR
- Patient must have developed intolerance to another epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor (TKI) of a severity necessitating permanent treatment withdrawal,
- **AND**
- Patient must have a WHO performance status of 2 or less.

**Population criteria:**
- Patient must have evidence of an activating epidermal growth factor receptor (EGFR) gene mutation known to confer sensitivity to treatment with...
EGFR tyrosine kinase inhibitors in tumour material.

**Authority required**

Stage IIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)

Treatment Phase: Continuing treatment

**Clinical criteria:**

- The treatment must be as monotherapy,
- AND
- Patient must have previously been issued with an authority prescription for this drug,
- AND
- Patient must not have progressive disease.

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**IMATINIB**

**Authority required**

Gastrointestinal stromal tumour

Treatment Phase: Initial treatment

**Clinical criteria:**

- The treatment must be adjuvant to complete surgical resection of primary gastrointestinal stromal tumour (GIST),
- AND
- Patient must be at high risk of recurrence following complete surgical resection of primary GIST,
- AND
- The condition must be histologically confirmed by the detection of CD117 on immunohistochemical staining,
- AND
- The treatment must not exceed a dose of 400 mg per day for a period of 36 months in total (initial plus continuing therapy).

Applications for authorisation of initial treatment must be in writing and must include:

1. a completed authority prescription form; and
2. a completed Imatinib Mesylate (Glivec) PBS Authority Application for Use in Adjuvant Treatment of Gastrointestinal Stromal Tumour - Supporting Information Form which includes the following:
   - (i) a copy of a pathology report from an Approved Pathology Authority supporting the diagnosis of a gastrointestinal stromal tumour and confirming the presence of CD117 on immunohistochemical staining; and
   - (ii) a copy of the pathology report must include the size and mitotic rate of the tumour, and the date of tumour resection must be documented, which must not be more than 3 months prior to the date of this application.

High risk of recurrence is defined as:

- Primary GIST greater than 5 cm with a mitotic count of greater than 5/50 high power fields (HPF); or
- Primary GIST greater than 10 cm with any mitotic rate; or
- Primary GIST with a mitotic count of greater than 10/50 HPF.

**Note**

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

**Note**

Any queries concerning patients who are enrolled on the Imatinib Compassionate Program may be directed to the Department of Human Services on 1800 700 270.
Clinical criteria:

The treatment must be adjuvant to complete surgical resection of primary gastrointestinal stromal tumour (GIST),

AND

Patient must be at high risk of recurrence following complete surgical resection of primary GIST,

AND

The treatment must not exceed a dose of 400 mg per day for a period of 36 months in total (initial plus continuing therapy),

AND

Patient must have previously been issued with an authority prescription for imatinib for adjuvant treatment following complete resection of primary GIST.

Applications for continuing therapy may be made by telephone.

Note

Authority approval for continuing treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Note

Written applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

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**IMATINIB**

**Authority required**

Initial PBS-subsidised treatment, for up to 3 months, of a patient with a metastatic or unresectable malignant gastrointestinal stromal tumour which has been histologically confirmed by the detection of CD117 on immunohistochemical staining.

Patients must commence treatment at a dose not exceeding 400 mg per day for at least 3 months. Authority prescriptions for a higher dose will not be approved during this initial 3 month treatment period.

Applications for authorisation must be in writing and must include:

1. a completed authority prescription form; and
2. a completed Imatinib Mesylate (Glivec) PBS Authority Application for Use in the Treatment of Metastatic or Unresectable Gastrointestinal Stromal Tumour - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
   i. a copy of a pathology report from an Approved Pathology Authority supporting the diagnosis of a gastrointestinal stromal tumour and confirming the presence of CD117 on immunohistochemical staining; and
   ii. a copy of the most recent (within 2 months of the application) computed tomography (CT) scan, magnetic resonance imaging (MRI) or ultrasound assessment of the tumour(s), including whether or not there is evidence of metastatic disease; and
   iii. where the application for authority to prescribe is being sought on the basis of an unresectable tumour, written evidence in support of that claim must be provided

**Authority required**

Continuing PBS-subsidised treatment, at a dose of up to 600 mg per day, of a patient with a metastatic or unresectable malignant gastrointestinal stromal tumour who has previously been issued with an authority prescription for this drug.

Applications for continuing treatment may be made by telephone (1800 700 270, hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Patients who have failed to respond or are intolerant to imatinib are no longer eligible to receive PBS-subsidised imatinib

**Note**

Any queries concerning the arrangements to prescribe imatinib mesylate may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe imatinib mesylate should be forwarded to:
Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
For the following diseases, written authority is required at initiation and for continuation:

Dermatofibrosarcoma protuberans;

Hypereosinophilic syndrome;

Chronic eosinophilic leukaemia;

Myelodysplastic or myeloproliferative disorder;

Aggressive systemic mastocytosis with eosinophilia.

Note

Patients with metastatic/unresectable disease who achieve a response to treatment at an imatinib dose of 400 mg per day should be continued at this dose and assessed for response at regular intervals. Patients who fail to achieve a response to 400 mg per day may have their dose increased to 600 mg per day. Authority applications for doses higher than 600 mg per day will not be approved.

A response to treatment is defined as a decrease from baseline in the sum of the products of the perpendicular diameters of all measurable lesions of 50% or greater. (Response definition based on the Southwest Oncology Group standard criteria, see Demetri et al. N Engl J Med 2002; 347: 472-80.)

Note

No applications for increased repeats will be authorised.

9111M
imatinib 100 mg tablet, 60
1 2 ..
1963.21 36.90 Glivec NV

9112N
imatinib 400 mg tablet, 30
1 2 ..
3779.71 36.90 Glivec NV

IMATINIB

Authority required

Initial treatment, as the sole PBS-subsidised therapy, of a patient in the chronic phase of chronic myeloid leukaemia expressing the Philadelphia chromosome or the transcript, BCR-ABL tyrosine kinase, and who has a primary diagnosis of chronic myeloid leukaemia.

Applications under this restriction will be limited to provide patients with a maximum of 18 months of therapy with dasatinib, imatinib or nilotinib from the date the first application for initial treatment was approved.

Patients should be commenced on a dose of imatinib mesylate of 400 mg (base) daily. Continuing therapy is dependent on patients demonstrating a response to imatinib mesylate therapy following the initial 18 months of treatment and at 12 monthly intervals thereafter.

Applications for authorisation must be in writing and must include:

1. a completed authority prescription form; and
2. a completed Chronic Myeloid Leukaemia - Chronic Phase, First Line - Supporting Information form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and
3. a pathology cytogenetic report conducted on peripheral blood or bone marrow supporting the diagnosis of chronic myeloid leukaemia to confirm eligibility for treatment, or a qualitative PCR report documenting the presence of the BCR-ABL transcript in either peripheral blood or bone marrow; and
4. a signed patient acknowledgement form

Authority required

Continuing treatment, as the sole PBS-subsidised therapy, of a patient who has received initial PBS-subsidised treatment with imatinib mesylate for the chronic phase of chronic myeloid leukaemia and who has demonstrated either a major cytogenetic response or less than 1% BCR-ABL level in the blood.

First continuing applications for authorisation must be in writing and must include:

1. a completed authority prescription form; and
2. demonstration of a response to treatment as evidenced by either:
   a major cytogenetic response [see Note explaining requirements]; or
   b a peripheral blood level of BCR-ABL of less than 1% on the international scale [see Note explaining requirements].

Second and subsequent authority applications for continuing therapy with imatinib mesylate may be made on the telephone by contacting Medicare Australia on 1800 700 720 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Patients must maintain a major cytogenetic response or have a peripheral blood BCR-ABL of less than 1% to receive continuing therapy

Note

Any queries concerning the arrangements to prescribe imatinib mesylate may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe imatinib mesylate should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs
From 1 April 2012, under the PBS, a patient will be able to be prescribed any of imatinib mesylate, dasatinib or nilotinib within treatment. Eligible patients may only swap between TKI agents if they have not failed prior PBS-subsidised treatment with that agent.

Patients are eligible for PBS-subsidised treatment with only one TKI agent at any one time and must not be receiving concomitant interferon alfa therapy. A peripheral blood BCR-ABL level of less than 1% has been demonstrated may receive authorisation for a further 12 months of treatment; and

(i) within 18 months of the commencement of treatment, at which time patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% is demonstrable by 18 months are eligible to receive continuing treatment.

(ii) at no greater than 12 month intervals thereafter, to demonstrate that the major cytogenetic response or peripheral blood BCR-ABL level of less than 1% has been sustained.

For the purposes of assessing response to PBS-subsidised treatment with imatinib mesylate, dasatinib or nilotinib either cytogenetic analysis indicating the number of Philadelphia positive [t (9;22)] cells in the bone marrow measured by standard karyotyping, or quantitative PCR indicating the relative level of BCR-ABL transcript in the peripheral blood using the international scale, must be submitted. For bone marrow analyses, where the standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe must be submitted. The cytogenetic or peripheral blood quantitative PCR analyses must be submitted within 18 months of the commencement of treatment with imatinib mesylate, dasatinib or nilotinib (patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% is demonstrable by 18 months are eligible to receive continuing treatment with that agent).

A major cytogenetic response is defined as less than 35% Philadelphia positive bone marrow cells. A peripheral blood BCR-ABL level of less than 1% on the international scale (Blood 108: 28-37, 2006) also indicates a response, at least the biological equivalent of a major cytogenetic response.


A major cytogenetic response is defined as less than 35% Philadelphia positive bone marrow cells.

A peripheral blood BCR-ABL level of less than 1% on the international scale (Blood 108: 28-37, 2006) also indicates a response, at least the biological equivalent of a major cytogenetic response.

7. Definitions of loss of response.

Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing tyrosine kinase inhibitor (TKI) therapy.

Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at
IMATINIB

Authority required

Treatment of patients in the accelerated phase of chronic myeloid leukaemia expressing the Philadelphia chromosome or the transcript, bcr-abl tyrosine kinase, and who have a primary diagnosis of chronic myeloid leukaemia. Progress to the accelerated phase is defined by the presence of 1 or more of the following:

(1) Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 15% but less than 30%; or
(2) Percentage of blasts plus promyelocytes in the peripheral blood or bone marrow greater than or equal to 30%; or
(3) Peripheral basophils greater than or equal to 20%; or
(4) Progressive splenomegaly to a size greater than or equal to 10 cm below the left costal margin to be confirmed on 2 occasions at least 4 weeks apart, or a greater than or equal to 50% increase in size below the left costal margin over 4 weeks; or
(5) Karyotypic evolution (chromosomal abnormalities in addition to a single Philadelphia chromosome).

Applications for authorisation must be in writing and must include:

(a) a completed authority prescription form; and
(b) a completed Imatinib Mesylate (Glivec) PBS Authority Application for Use in the Treatment of Chronic Myeloid Leukaemia - Supporting Information form, stating which of the above criteria are satisfied by the patient; and
(c) a copy of the confirming pathology report from an Approved Pathology Authority in the case of criteria (1), (2), (3) and (5) above, or details of the dates of assessments in the case of progressive splenomegaly

Authority required

Treatment of patients in the blast phase of chronic myeloid leukaemia expressing the Philadelphia chromosome or the transcript, bcr-abl tyrosine kinase, and who have a primary diagnosis of chronic myeloid leukaemia. Progress to myeloid blast crisis is defined as either:

(1) Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 30%; or
(2) Extramedullary involvement other than spleen and liver.

Applications for authorisation must be in writing and must include:

(a) a completed authority prescription form; and
(b) a completed Imatinib Mesylate (Glivec) PBS Authority Application for Use in the Treatment of Chronic Myeloid Leukaemia - Supporting Information form, stating which of the above criteria are satisfied by the patient; and
(c) a copy of the confirming pathology report from an Approved Pathology Authority in the case of criterion (1) above, or details of the date of assessment in the case of extramedullary involvement

Authority required

Continuing treatment of patients with chronic myeloid leukaemia expressing the Philadelphia chromosome or the transcript, bcr-abl tyrosine kinase, where the patient has previously received PBS-subsidised treatment with imatinib mesylate of the accelerated phase of chronic myeloid leukaemia

Authority required

Continuing treatment of patients with chronic myeloid leukaemia expressing the Philadelphia chromosome or the transcript, bcr-abl tyrosine kinase, where the patient has previously received PBS-subsidised treatment with imatinib mesylate of the blast phase of chronic myeloid leukaemia

Note

Any queries concerning the arrangements to prescribe imatinib mesylate may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe imatinib mesylate should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

For the following diseases, written authority is required at initiation and for continuation:
Dermatofibrosarcoma protuberans;
Hypereosinophilic syndrome;
Chronic eosinophilic leukaemia;
Myelodysplastic or myeloproliferative disorder;
IMATINIB

Authority required

Initial treatment in combination with chemotherapy as induction or consolidation of a newly diagnosed patient with acute lymphoblastic leukaemia (ALL) bearing the Philadelphia chromosome or expressing the transcript, BCR-ABL.

The first authority application must be made in writing and must include:

(a) a completed authority prescription form; and
(b) a completed Acute Lymphoblastic Leukaemia Imatinib PBS Authority Application - Supporting Information Form; and
(c) a pathology cytogenetic report conducted on peripheral blood or bone marrow supporting the diagnosis of acute lymphoblastic leukaemia to confirm eligibility for treatment, with either cytogenetic evidence of the Philadelphia chromosome, or a qualitative PCR report documenting the presence of the BCR-ABL transcript in either peripheral blood or bone marrow. (The date of the relevant pathology report needs to be provided); and
(d) a signed patient acknowledgement

Authority required

Initial treatment of a patient with acute lymphoblastic leukaemia bearing the Philadelphia chromosome or expressing the transcript BCR-ABL who was previously treated with imatinib mesylate under the Imatinib Compassionate Program and who meets all the PBS criteria.

The first authority application must be made in writing and must include:

(a) a completed authority prescription form; and
(b) a completed Acute Lymphoblastic Leukaemia Imatinib PBS Authority Application - Supporting Information Form; and
(c) a pathology cytogenetic report conducted on peripheral blood or bone marrow supporting the diagnosis of acute lymphoblastic leukaemia to confirm eligibility for treatment, with either cytogenetic evidence of the Philadelphia chromosome, or a qualitative PCR report documenting the presence of the BCR-ABL transcript in either peripheral blood or bone marrow. (The date of the relevant pathology report needs to be provided); and
(d) a signed patient acknowledgement

Authority required

Continuing treatment in combination with chemotherapy as maintenance of first complete remission of patients with acute lymphoblastic leukaemia bearing the Philadelphia chromosome or expressing the transcript, BCR-ABL.

Authority applications for continuing treatment may be made by telephone to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Imatinib mesylate is available with a lifetime maximum of 24 months for continuing treatment with imatinib mesylate therapy for patients with acute lymphoblastic leukaemia reimbursed through the PBS.

Any queries concerning the arrangements to prescribe imatinib mesylate beyond 24 months may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday)

Note

Any queries concerning the arrangements to prescribe imatinib mesylate may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe imatinib mesylate should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

For the following diseases, written authority is required at initiation and for continuation:

Dermatofibrosarcoma protuberans;

Hypereosinophilic syndrome;

Chronic eosinophilic leukaemia;

Myelodysplastic or myeloproliferative disorder;

Aggressive systemic mastocytosis with eosinophilia.
Allogeneic stem cell transplantation is the preferred therapy for eligible patients achieving a complete remission of Philadelphia positive acute lymphoblastic leukaemia.

No applications for increased repeats will be authorised.

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**IMATINIB**

**Authority required**

Initial PBS-subsidised treatment of a patient with unresectable, locally recurrent or metastatic dermatofibrosarcoma protuberans.

Maximum dose: 800 mg per day.

(1) Where the application for authority to prescribe is being sought on the basis of unresectable tumour, written evidence in support of that claim must be provided; and

(2) Where the application for authority to prescribe is being sought on the basis of locally recurrent disease, the site of the local recurrence must be specified; and

(3) Where the application for authority to prescribe is being sought on the basis of metastatic disease, the site(s) of metastatic disease must be provided.

Applications for authorisation for initial treatment must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Rare Diseases Imatinib PBS Authority Application - Supporting Information Form; and

(c) a signed patient acknowledgement

**Authority required**

Continuing PBS-subsidised treatment of a patient with unresectable, locally recurrent or metastatic dermatofibrosarcoma protuberans who has previously been issued with an authority prescription for imatinib and who has demonstrated a response, but whose disease remains unresectable.

Maximum dose: 800 mg per day.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Rare Diseases Imatinib PBS Authority Application - Supporting Information Form; and

(c) a statement that the disease has not progressed on imatinib therapy

**Note**

Any queries concerning the arrangements to prescribe imatinib mesylate may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe imatinib mesylate should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

For the following diseases, written authority is required at initiation and for continuation:

- Dermatofibrosarcoma protuberans;
- Hypereosinophilic syndrome;
- Chronic eosinophilic leukaemia;
- Myelodysplastic or myeloproliferative disorder;
- Aggressive systemic mastocytosis with eosinophilia.

**Note**

No applications for increased repeats will be authorised.

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ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

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</tbody>
</table>

**Authority required**

Initial PBS-subsidised treatment of a patient with hypereosinophilic syndrome or chronic eosinophilic leukaemia requiring treatment and confirmed to carry the FIP1L1-PDGFRα fusion gene.

Maximum dose: 400 mg per day.

Applications for authorisation for initial treatment must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Rare Diseases Imatinib PBS Authority Application - Supporting Information Form; and

(c) a copy of the pathology report confirming the presence of the FIP1L1-PDGFRα fusion gene; and

(d) a copy of the full blood examination report confirming the presence of hypereosinophilic syndrome or chronic eosinophilic leukaemia; and

(e) details of organ involvement requiring treatment, including a copy of the radiology, nuclear medicine, respiratory function or anatomical pathology reports as appropriate; and

(f) a signed patient acknowledgement

**Authority required**

Continuing PBS-subsidised treatment of a patient with hypereosinophilic syndrome or chronic eosinophilic leukaemia who has previously been issued with an authority prescription for imatinib and who has achieved and maintained a complete haematological response.

Maximum dose: 400 mg per day.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Rare Diseases Imatinib PBS Authority Application - Supporting Information Form; and

(c) a copy of the full blood examination report which demonstrates a complete haematological response, with a normal eosinophil count; and

(d) a statement that the disease has not progressed on imatinib therapy

**Note**

Any queries concerning the arrangements to prescribe imatinib mesylate may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe imatinib mesylate should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

For the following diseases, written authority is required at initiation and for continuation:

Dermatofibrosarcoma protuberans;

Hypereosinophilic syndrome;

Chronic eosinophilic leukaemia;

Myelodysplastic or myeloproliferative disorder;

Aggressive systemic mastocytosis with eosinophilia.

**Note**

No applications for increased repeats will be authorised.

**IMATINIB**

**Authority required**

Initial PBS-subsidised treatment of a patient with a myelodysplastic or myeloproliferative disorder where:

(1) there is confirmed evidence of a platelet-derived growth factor receptor (PDGFR) gene re-arrangement either by standard karyotyping, or FISH or PDGFRα fusion gene transcript; and

(2) the patient has previously failed an adequate trial of one or more of the following conventional therapies:

— cytarabine;

— etoposide;

— hydroxyurea.

Maximum dose: 400 mg per day.
Applications for authorisation for initial treatment must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Rare Diseases Imatinib PBS Authority Application - Supporting Information Form; and

(c) a copy of the pathology report confirming the platelet-derived growth factor receptor (PDGFR) gene re-arrangement; and

(d) a copy of the bone marrow biopsy report which demonstrates the presence of a myelodysplastic or myeloproliferative disorder; and

(e) details of the prior therapy trialled and the response; and

(f) a signed patient acknowledgement

**Authority required**

Continuing PBS-subsidised treatment of a patient with a PDGFRB fusion gene-positive myelodysplastic or myeloproliferative disorder who has previously been issued with an authority prescription for imatinib and who has demonstrated a complete haematological response.

Maximum dose: 400 mg per day.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Rare Diseases Imatinib PBS Authority Application - Supporting Information Form; and

(c) a copy of the full blood examination report which demonstrates a complete haematological response; and

(d) a statement that the disease has not progressed on imatinib therapy

**Note**

Any queries concerning the arrangements to prescribe imatinib mesylate may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe imatinib mesylate should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

For the following diseases, written authority is required at initiation and for continuation:

Dermatofibrosarcoma protuberans;

Hypereosinophilic syndrome;

Chronic eosinophilic leukaemia;

Myelodysplastic or myeloproliferative disorder;

Aggressive systemic mastocytosis with eosinophilia.

**Note**

No applications for increased repeats will be authorised.

9176Y imatinib 100 mg tablet, 60 1 2 .. 1963.21 36.90 Glivec NV

9177B imatinib 400 mg tablet, 30 1 2 .. 3779.71 36.90 Glivec NV

**IMATINIB**

**Authority required**

Initial PBS-subsidised treatment of a patient with aggressive systemic mastocytosis with eosinophilia where:

(1) there is confirmed evidence of the FIP1L1-PDGFR fusion gene; and

(2) the patient has previously failed an adequate trial of one or more of the following conventional therapies:

— corticosteroids;

— hydroxyurea.

Maximum dose: 400 mg per day.

Applications for authorisation for initial treatment must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Rare Diseases Imatinib PBS Authority Application - Supporting Information Form; and

(c) a copy of the pathology report confirming the presence of the FIP1L1-PDGFR fusion gene; and

(d) a copy of the bone marrow biopsy report and/or other tissue biopsy report confirming the diagnosis of aggressive systemic mastocytosis and a copy of the full blood examination report demonstrating eosinophilia; and
(e) details of symptomatic organ involvement requiring treatment, including a copy of the radiology, nuclear medicine, respiratory function or anatomical pathology reports as appropriate; and

(f) details of prior treatment trialled and the response; and

(g) a signed patient acknowledgement

**Authority required**

Continuing PBS-subsidised treatment of a patient with aggressive systemic mastocytosis confirmed to carry the FIP1L1-PDGFRα fusion gene, who has previously been issued with an authority prescription for imatinib and who has demonstrated a complete haematological response.

Maximum dose: 400 mg per day.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Rare Diseases Imatinib PBS Authority Application - Supporting Information Form; and

(c) a copy of the full blood examination report which demonstrates a complete haematological response; and

(d) a statement that the disease has not progressed on imatinib therapy

**Note**

Any queries concerning the arrangements to prescribe imatinib mesylate may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe imatinib mesylate should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

For the following diseases, written authority is required at initiation and for continuation:

- Dermatofibrosarcoma protuberans;
- Hypereosinophilic syndrome;
- Chronic eosinophilic leukaemia;
- Myelodysplastic or myeloproliferative disorder;
- Aggressive systemic mastocytosis with eosinophilia.

**Note**

No applications for increased repeats will be authorised.

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**LAPATINIB**

**Authority required**

Initial treatment, in combination with capecitabine, of a patient with HER2 positive metastatic breast cancer (equivalent to Stage IIIIC or Stage IV) who has received prior therapy with a taxane, for at least 3 cycles, and whose disease has progressed despite treatment with trastuzumab for metastatic disease.

Authority applications for initial treatment must be made in writing and must include:

(a) a completed authority prescription form;

(b) a pathology report demonstrating HER2 positivity has been demonstrated by in situ hybridisation (ISH);

(c) date of last treatment with a taxane and total number of cycles;

(d) a signed patient acknowledgment;

(e) dates of treatment with trastuzumab; and

(f) date of demonstration of progression whilst on treatment with trastuzumab

**Authority required**

Continuing treatment, in combination with capecitabine, of a patient with HER2 positive metastatic breast cancer who has previously received treatment with PBS-subsidised lapatinib and who does not have progressive disease.

Authority applications must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a statement from the prescribing doctor that the disease has not progressed
### Antineoplastic and Immunomodulating Agents

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<td>Tykerb</td>
<td>Any queries concerning the arrangements to prescribe lapatinib may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Lapatinib should not be used in patients with a left ventricular ejection fraction (LVEF) of less than 45% or with symptomatic heart failure. Cardiac function must be tested by a suitable method including, for example, ECHO or MUGA, prior to seeking the initial authority approval and then at 3 monthly intervals during treatment. Lapatinib is not PBS-subsidised when used in combination with Commonwealth-subsidised trastuzumab. If disease progression occurs, the prescribing doctor must contact Medicare Australia within one week on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) and lapatinib treatment must be ceased immediately.</td>
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### Nilotinib

**Authority required**

Initial treatment, as the sole PBS-subsidised therapy, of a patient in the chronic phase of chronic myeloid leukaemia expressing the Philadelphia chromosome or the transcript, BCR-ABL tyrosine kinase, and who has a primary diagnosis of chronic myeloid leukaemia.

Applications under this restriction will be limited to provide patients with a maximum of 18 months of therapy with dasatinib, imatinib or nilotinib from the date the first application for initial treatment was approved.

Patients should be commenced on a dose of nilotinib of 300 mg twice daily. Continuing therapy is dependent on patients demonstrating a response to nilotinib therapy following the initial 18 months of treatment and at 12 monthly intervals thereafter.

Applications for authorisation must be in writing and must include:

1. a completed authority prescription form; and  
2. a completed Chronic Myeloid Leukaemia - Chronic Phase, First Line - Supporting Information form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and  
3. a pathology cytogenetic report conducted on peripheral blood or bone marrow supporting the diagnosis of chronic myeloid leukaemia to confirm eligibility for treatment, or a qualitative PCR report documenting the presence of the BCR-ABL transcript in either peripheral blood or bone marrow; and  
4. a signed patient acknowledgement form

**Authority required**

Continuing treatment, as the sole PBS-subsidised therapy, of a patient who has received initial PBS-subsidised treatment with nilotinib for the chronic phase of chronic myeloid leukaemia and who has demonstrated either a major cytogenetic response or less than 1% BCR-ABL level in the blood.

Applications for authorisation must be in writing and must include:

1. a completed authority prescription form; and  
2. demonstration of continued response to treatment as evidenced by either:  
   a. major cytogenetic response [see Note explaining requirements]. Where this has been supplied within the previous 12 months, only the date of the relevant pathology report need be provided; or  
   b. a peripheral blood level of BCR-ABL of less than 1% on the international scale [see Note explaining requirements]. Where this has been supplied within the previous 12 months, only the date of the relevant pathology report need be provided

**Note**

Any queries concerning the arrangements to prescribe nilotinib may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au. Applications for authority to prescribe nilotinib should be forwarded to: Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826
During the initial 18 month treatment period, switching between approved first-line agents may only occur for reasons of intolerance, not failure of response.

2. Continuing treatment with imatinib mesylate - first-line

First continuing applications are to be written and must include a pathology report demonstrating the patient has responded to the initial course of treatment.

Second and subsequent authority applications for continuing therapy with imatinib mesylate may be made on the telephone by contacting Medicare Australia on 1800 700 720 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Patients must maintain a major cytogenetic response or have a peripheral blood BCR-ABL of less than 1% to receive continuing therapy.

3. Continuing treatment with dasatinib or nilotinib - first-line

All continuing applications are to be written and must include a pathology report demonstrating the patient has responded to PBS-subsidised treatment as follows:

(i) within 18 months of the commencement of treatment, at which time patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% has been demonstrated may receive authorisation for a further 12 months of treatment; and

(ii) at no greater than 12 month intervals thereafter, to demonstrate that the major cytogenetic response or peripheral blood BCR-ABL level of less than 1% has been sustained.

4. For imatinib mesylate, dasatinib and nilotinib

During continuing therapy beyond the initial 18 month treatment period, switching between approved first-line agents may only occur for reason of intolerance. Where there is failure of response, switching may only occur through application for prescription of second-line agents.

Where a patient has previously received PBS-subsidised treatment with imatinib mesylate, dasatinib or nilotinib no approval will be granted for PBS-subsidised re-treatment in the chronic phase of chronic myeloid leukaemia, where that patient has at any time failed to meet the response criteria whilst on that TKI agent.

5. Authority approval requirements.

Response criteria to initial treatment with imatinib mesylate, dasatinib or nilotinib:

For the purposes of assessing response to PBS-subsidised treatment with imatinib mesylate, dasatinib or nilotinib either cytogenetic analysis indicating the number of Philadelphia positive [t (9;22)] cells in the bone marrow measured by standard karyotyping, or qualitative PCR indicating the relative level of BCR-ABL transcript in the peripheral blood using the international scale, must be submitted. For bone marrow analyses, where the standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe must be submitted. The cytogenetic or peripheral blood quantitative PCR analyses must be submitted within 18 months of the commencement of treatment with imatinib mesylate, dasatinib or nilotinib (patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% is demonstrable by 18 months are eligible to receive continuing treatment with that agent).


A major cytogenetic response is defined as less than 35% Philadelphia positive bone marrow cells.

A peripheral blood BCR-ABL level of less than 1% on the international scale (Blood 108: 28-37, 2006) also indicates a response, at least the biological equivalent of a major cytogenetic response.

7. Definitions of loss of response.

Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing tyrosine kinase inhibitor (TKI) therapy.

Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing tyrosine kinase inhibitor therapy.

Note

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of tyrosine kinase inhibitors (TKI) agents for the chronic phase of chronic myeloid leukaemia. Where the term TKI agent appears in the following notes and restrictions it refers to imatinib mesylate, dasatinib or nilotinib.

Patients are eligible for PBS-subsidised treatment with only one TKI agent at any one time and must not be receiving concomitant interferon alfa therapy. Eligible patients may only swap between TKI agents if they have not failed prior PBS-subsidised treatment with that agent.

1. Initial treatment - imatinib mesylate, dasatinib and nilotinib

From 1 April 2012, under the PBS, a patient will be able to be prescribed any of imatinib mesylate, dasatinib or nilotinib within the initial 18 month treatment period, as long as only one agent is used at a time and providing the patient has not failed to respond to any one of these TKIs.

During the initial 18 month treatment period, switching between approved first-line agents may only occur for reasons of intolerance, not failure of response.

2. Continuing treatment with imatinib mesylate - first-line

First continuing applications are to be written and must include a pathology report demonstrating the patient has responded to the initial course of treatment.

Second and subsequent authority applications for continuing therapy with imatinib mesylate may be made on the telephone by contacting Medicare Australia on 1800 700 720 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Patients must maintain a major cytogenetic response or have a peripheral blood BCR-ABL of less than 1% to receive continuing therapy.

3. Continuing treatment with dasatinib or nilotinib - first-line

All continuing applications are to be written and must include a pathology report demonstrating the patient has responded to PBS-subsidised treatment as follows:

(i) within 18 months of the commencement of treatment, at which time patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% has been demonstrated may receive authorisation for a further 12 months of treatment; and

(ii) at no greater than 12 month intervals thereafter, to demonstrate that the major cytogenetic response or peripheral blood BCR-ABL level of less than 1% has been sustained.

4. For imatinib mesylate, dasatinib and nilotinib

During continuing therapy beyond the initial 18 month treatment period, switching between approved first-line agents may only occur for reason of intolerance. Where there is failure of response, switching may only occur through application for prescription of second-line agents.

Where a patient has previously received PBS-subsidised treatment with imatinib mesylate, dasatinib or nilotinib no approval will be granted for PBS-subsidised re-treatment in the chronic phase of chronic myeloid leukaemia, where that patient has at any time failed to meet the response criteria whilst on that TKI agent.

5. Authority approval requirements.

Response criteria to initial treatment with imatinib mesylate, dasatinib or nilotinib:

For the purposes of assessing response to PBS-subsidised treatment with imatinib mesylate, dasatinib or nilotinib either cytogenetic analysis indicating the number of Philadelphia positive [t (9;22)] cells in the bone marrow measured by standard karyotyping, or quantitative PCR indicating the relative level of BCR-ABL transcript in the peripheral blood using the international scale, must be submitted. For bone marrow analyses, where the standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe must be submitted. The cytogenetic or peripheral blood quantitative PCR analyses must be submitted within 18 months of the commencement of treatment with imatinib mesylate, dasatinib or nilotinib (patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% is demonstrable by 18 months are eligible to receive continuing treatment with that agent).


A major cytogenetic response is defined as less than 35% Philadelphia positive bone marrow cells.

A peripheral blood BCR-ABL level of less than 1% on the international scale (Blood 108: 28-37, 2006) also indicates a response, at least the biological equivalent of a major cytogenetic response.

7. Definitions of loss of response.

Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing tyrosine kinase inhibitor (TKI) therapy.

Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing tyrosine kinase inhibitor therapy.
— failure to achieve a haematological response after a minimum of 3 months therapy with imatinib or dasatinib for patients initially treated in chronic phase; or

— failure to achieve any cytogenetic response after a minimum of 6 months therapy with imatinib or dasatinib for patients initially treated in chronic phase as demonstrated on bone marrow biopsy by presence of greater than 95% Philadelphia chromosome positive cells; or

— failure to achieve a major cytogenetic response or a peripheral blood BCR-ABL level of less than 1% after a minimum of 12 months therapy with imatinib or dasatinib; OR

(ii) Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing imatinib or dasatinib therapy; OR

(iii) Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing imatinib or dasatinib therapy; OR

(iv) Development of accelerated phase in a patient previously prescribed imatinib or dasatinib for the chronic phase of chronic myeloid leukaemia. Accelerated phase is defined by the presence of 1 or more of the following:

(1) Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 15% but less than 30%; or

(2) Percentage of blasts plus promyelocytes in the peripheral blood or bone marrow greater than or equal to 30%, provided that blast count is less than 30%; or

(3) Peripheral basophils greater than or equal to 20%; or

(4) Progressive splenomegaly to a size greater than or equal to 10 cm below the left costal margin to be confirmed on 2 occasions at least 4 weeks apart, or a greater than or equal to 50% increase in size below the left costal margin over 4 weeks; or

(5) Karyotypic evolution (chromosomal abnormalities in addition to a single Philadelphia chromosome); OR

(v) Disease progression (defined as a greater than or equal to 50% increase in peripheral white blood cell count, blast count, basophils or platelets) during first-line imatinib or dasatinib therapy in patients with accelerated phase chronic myeloid leukaemia, provided that blast crisis has been excluded on bone marrow biopsy.

Patients should be commenced on a dose of nilotinib of 400 mg twice daily. Continuing therapy is dependent on patients demonstrating a major cytogenetic response to nilotinib therapy or a peripheral blood BCR-ABL level of less than 1% within 18 months and thereafter at 12 monthly intervals.

Applications for authorisation must be in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Chronic Myeloid Leukaemia - Second and Third Line - Supporting Information Form; and

(c) a signed patient acknowledgement; and

(d) a bone marrow biopsy pathology report demonstrating the patient has active chronic myeloid leukaemia, either manifest as cytogenetic evidence of the Philadelphia chromosome, or RT-PCR level of BCR-ABL transcript greater than 0.1% on the international scale. (The date of the relevant pathology report needs to be provided); and

(e) where there has been a loss of response to imatinib or dasatinib, a copy of the current confirming pathology report(s) from an Approved Pathology Authority or details of the dates of assessment in the case of progressive splenomegaly or extramedullary involvement.

Authority required

Continuing treatment, as the sole PBS-subsidised therapy, of a patient who has received initial PBS-subsidised treatment with nilotinib for chronic myeloid leukaemia, and who has demonstrated either a major cytogenetic response, or less than 1% BCR-ABL level in the blood, to dasatinib in the preceding 18 months and thereafter at 12 monthly intervals.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Chronic Myeloid Leukaemia - Second and Third Line - Application Form for continuing treatment; and

(3) demonstration of continued response to treatment as evidenced by either:

(a) major cytogenetic response [see Note explaining definitions of response]. Where this has been supplied within the previous 12 months (or 18 months for the initial supply), only the date of the relevant pathology report needs to be provided; or

(b) a peripheral blood level of BCR-ABL of less than 1% on the international scale [see Note explaining definitions of response]. Where this has been supplied within the previous 12 months (or 18 months for the initial supply), only the date of the relevant pathology report needs to be provided.

Note

Any queries concerning the arrangements to prescribe nilotinib may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Applications for authority to prescribe nilotinib should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of tyrosine kinase inhibitors (TKI) agents for all phases of chronic myeloid leukaemia. Where the term TKI agent appears in the following notes and restrictions it refers to dasatinib or nilotinib. Imatinib mesylate is not approved for use in second or third line treatment.

Patients are eligible for PBS-subsidised treatment with only one of dasatinib or nilotinib at any one time and must not be receiving concomitant interferon alfa therapy. Eligible patients may only swap between these agents if they have not failed prior PBS-subsidised treatment with that agent.

Nilotinib is not approved for patients in blast crisis.

1. Initial second line treatment

From 1 April 2012, under the PBS, a patient will be able to be prescribed either dasatinib or nilotinib within the initial 18 month treatment period as second-line therapy, as long as only one agent is approved at a time and providing the patient did not fail that drug as first-line therapy.

During the initial 18 month treatment period, switching between approved second-line agents may only occur for reasons of intolerance, not failure of response.

2. Initial third line treatment

Third-line treatment with a TKI can only be approved when imatinib is used for first-line treatment. Patients will only be approved for PBS-subsidised treatment with one third-line agent.

From 1 April 2012, under the PBS, a patient will be able to be prescribed either dasatinib or nilotinib providing the patient did not fail that drug as first or second line therapy and for nilotinib the patient is not in blast crisis.

3. Continuing treatment for second and third line treatment

All continuing applications are to be written and must include a pathology report demonstrating the patient has responded to PBS-subsidised treatment as follows:

(i) within 18 months of the commencement of treatment, at which time patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% has been demonstrated may receive authorisation for a further 12 months of treatment; and

(ii) at no greater than 12 month intervals thereafter, to demonstrate that the major cytogenetic response or peripheral blood BCR-ABL level of less than 1% has been sustained.

During second line continuing treatment beyond the initial 18 month treatment period, switching between approved second line TKI agents may only occur for reason of intolerance. Where there is failure of response, switching may only occur through application for prescription of a third line agent.

4. Authority approval requirements.

Response criteria to initial treatment with dasatinib or nilotinib:

For the purposes of assessing response to PBS-subsidised treatment with dasatinib or nilotinib, either cytogenetic analysis indicating the number of Philadelphia positive (t(9;22)) cells in the bone marrow measured by standard karyotyping, or quantitative PCR indicating the relative level of BCR-ABL transcript in the peripheral blood using the international scale, must be submitted. For bone marrow analyses, where the standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe must be submitted. The cytogenetic or peripheral blood quantitative PCR analyses must be submitted within 18 months of the commencement of treatment with dasatinib or nilotinib (patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% is demonstrable by 18 months are eligible to receive continuing treatment with that agent).

5. Definitions of response.

A major cytogenetic response is defined as less than 35% Philadelphia positive bone marrow cells.

A peripheral blood BCR-ABL level of less than 1% on the international scale (Blood 108: 28-37, 2006) also indicates a response, at least the biological equivalent of a major cytogenetic response.


Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing tyrosine kinase inhibitor (TKI) therapy.

Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing tyrosine kinase inhibitor therapy.

### PAZOPANIB

**Authority required**

Advanced (unresectable and/or metastatic) soft tissue sarcoma

**Treatment Phase:** Continuing treatment beyond 3 months

**Clinical criteria:**

Patient must have previously been issued with an authority prescription for pazopanib.

AND

Patient must have stable or responding disease according to the Response Evaluation Criteria In Solid Tumours (RECIST), AND
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**PAZOPANIB**

**Authority required**
Stage IV clear cell variant renal cell carcinoma (RCC)

Treatment Phase: Continuing treatment beyond 3 months

**Clinical criteria:**
- Patient must have previously been issued with an authority prescription for pazopanib,
- AND
- Patient must have stable or responding disease according to the Response Evaluation Criteria In Solid Tumours (RECIST),
- AND
- Patient must require dose adjustment,
- AND
- The treatment must be the sole PBS-subsidised tyrosine kinase inhibitor therapy for this condition.

**Note**
- Patients who have progressive disease with pazopanib are no longer eligible for PBS-subsidised pazopanib.
- Patients who have progressive disease on sunitinib are not eligible to receive PBS-subsidised pazopanib.

**Note**
- Response Evaluation Criteria In Solid Tumours (RECIST) is defined as follows:
  - Complete response (CR) is disappearance of all target lesions.
  - Partial response (PR) is a 30% decrease in the sum of the longest diameter of target lesions.
  - Progressive disease (PD) is a 20% increase in the sum of the longest diameter of target lesions.
  - Stable disease (SD) is small changes that do not meet above criteria.

**Note**
Special Pricing Arrangements apply.

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Patient must have a WHO performance status of 2 or less,  
AND  
Patient must have received prior chemotherapy treatment including an anthracycline,  
AND  
Patient must not have received prior treatment with an angiogenesis inhibitor,  
AND  
The treatment must be the sole PBS-subsidised therapy for this condition.  
Patient must not have any of the following conditions:  
adipocytic soft tissue sarcoma;  
gastrointestinal stromal tumour (GIST);  
rhabdomyosarcoma other than alveolar or pleomorphic;  
chondrosarcoma;  
osteosarcoma;  
Ewings tumour/primitive neuroectodermal tumour;  
dermofibromatosis sarcoma protuberans;  
inflammatory myofibroblastic sarcoma;  
malignant mesothelioma;  
mixed mesodermal tumour of the uterus.  
The authority application must be made in writing.  

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

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

Note  
Special Pricing Arrangements apply.

### PAZOPANIB

**Authority required**  
Advanced (unresectable and/or metastatic) soft tissue sarcoma  

**Clinical criteria:**  
Patient must have previously been issued with an authority prescription for pazopanib,  
AND  
Patient must have stable or responding disease according to the Response Evaluation Criteria In Solid Tumours (RECIST),  
AND  
The treatment must be the sole PBS-subsidised therapy for this condition.  
Applications for continuing therapy may be made by telephone.  

Note  
Response Evaluation Criteria In Solid Tumours (RECIST) is defined as follows:  
Complete response (CR) is disappearance of all target lesions.  
Partial response (PR) is a 30% decrease in the sum of the longest diameter of target lesions.  
Progressive disease (PD) is a 20% increase in the sum of the longest diameter of target lesions.  
Stable disease (SD) is small changes that do not meet above criteria.  

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

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

Note  
Special Pricing Arrangements apply.
PAZOPANIB

Authority required
Stage IV clear cell variant renal cell carcinoma (RCC)

Treatment Phase: Initial treatment

Clinical criteria:
Patient must meet the Memorial Sloan Kettering Cancer Centre (MSKCC) low to intermediate risk group criteria,

AND

Patient must have a WHO performance status of 2 or less,

AND

The treatment must be the sole PBS-subsidised tyrosine kinase inhibitor therapy for this condition.

Patients who have progressive disease on sunitinib are not eligible to receive PBS-subsidised pazopanib.

Note
Patients who have developed intolerance to sunitinib of a severity necessitating permanent treatment withdrawal are eligible to receive PBS-subsidised pazopanib.

Note
Patients who have progressive disease with pazopanib are no longer eligible for PBS-subsidised pazopanib.

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

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

Note
Special Pricing Arrangements apply.

PAZOPANIB

Authority required
Stage IV clear cell variant renal cell carcinoma (RCC)

Treatment Phase: Continuing treatment beyond 3 months

Clinical criteria:
Patient must have previously been issued with an authority prescription for pazopanib,

AND

Patient must have stable or responding disease according to the Response Evaluation Criteria In Solid Tumours (RECIST),

AND

The treatment must be the sole PBS-subsidised tyrosine kinase inhibitor therapy for this condition.

Note
Patients who have progressive disease with pazopanib are no longer eligible for PBS-subsidised pazopanib.

Note
Patients who have progressive disease on sunitinib are not eligible to receive PBS-subsidised pazopanib.

Note
Response Evaluation Criteria In Solid Tumours (RECIST) is defined as follows:
Complete response (CR) is disappearance of all target lesions.
Partial response (PR) is a 30% decrease in the sum of the longest diameter of target lesions.
Progressive disease (PD) is a 20% increase in the sum of the longest diameter of target lesions.
Stable disease (SD) is small changes that do not meet above criteria.

Note
Special Pricing Arrangements apply.

Authority required
### ANTI NEOPLASTIC AND IMMUNOMODULATING AGENTS

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<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
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</table>
|      | Stage IV clear cell variant renal cell carcinoma (RCC) Treatment Phase: Initial treatment  
**Clinical criteria:**  
Patient must have been receiving treatment with pazopanib prior to 1 October 2012,  
**AND**  
The treatment must be the sole PBS-subsidised tyrosine kinase inhibitor therapy for this condition.  
**Note**  
Patients who have progressive disease with pazopanib are no longer eligible for PBS-subsidised pazopanib.  
**Note**  
Special Pricing Arrangements apply.  
| 2034C | pazopanib 200 mg tablet, 90 | 1 | 5 | .. | 3542.16 | 36.90 | 36.90 | Votrient | GK |
| 2035D | pazopanib 400 mg tablet, 60 | 1 | 5 | .. | 4673.98 | 36.90 | 36.90 | Votrient | GK |

**SORAFENIB**  
**Authority required (STREAMLINED)**  
4230  
Advanced Barcelona Clinic Liver Cancer Stage C hepatocellular carcinoma  
Treatment Phase: Initial  
**Clinical criteria:**  
The treatment must be the sole PBS-subsidised therapy for this condition,  
**AND**  
Patient must have a WHO performance status of 2 or less,  
**AND**  
Patient must have Child Pugh class A.  
**Authority required (STREAMLINED)**  
4234  
Advanced Barcelona Clinic Liver Cancer Stage C hepatocellular carcinoma  
Treatment Phase: Continuing  
**Clinical criteria:**  
The treatment must be the sole PBS-subsidised therapy for this condition,  
**AND**  
Patient must have previously been treated with PBS-subsidised sorafenib,  
**AND**  
Patient must not have progressive disease.  
**Note**  
Sorafenib is not PBS-subsidised for adjunctive treatment after resection, ablation or chemoembolization.  
Sorafenib is not PBS-subsidised for maintenance therapy after disease progression.  
**Note**  
No increase in the maximum quantity or number of units may be authorised.  
**Note**  
No increase in the maximum number of repeats may be authorised.  
**Note**  
Special Pricing Arrangements apply.  
| 9380Q | sorafenib 200 mg tablet, 60 | 2 | 2 | .. | *6457.42 | 36.90 | Nexavar | BN |

**SUNITINIB**  
**Authority required**  
Metastatic or unresectable, well-differentiated malignant pancreatic neuroendocrine tumour (pNET)  
Treatment Phase: Initial treatment  
**Clinical criteria:**  
Patient must be symptomatic (despite somatostatin analogues); OR  
Patient must have disease progression,
### ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

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### SUNITINIB

**Authority required**

Stage IV clear cell variant renal cell carcinoma (RCC)

**Clinical criteria:**

Patient must meet the Memorial Sloan Kettering Cancer Centre (MSKCC) low to intermediate risk group criteria,

AND

Patient must have a WHO performance status of 2 or less,

AND

The treatment must be the sole PBS-subsidised tyrosine kinase inhibitor therapy for this condition.

Patients who have developed progressive disease on pazopanib are not eligible to receive PBS-subsidised sunitinib.

**Note**

Patients who have developed intolerance to pazopanib of a severity necessitating permanent treatment withdrawal are eligible to receive PBS-subsidised sunitinib.
Patients who have progressive disease with sunitinib are no longer eligible for PBS-subsidised sunitinib.

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

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

**Note**
Special Pricing Arrangements apply.

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</table>

**SUNITINIB**

**Authority required**

Stage IV clear cell variant renal cell carcinoma (RCC)

Treatment Phase: Continuing treatment beyond 3 months

**Clinical criteria:**

Patient must have previously been issued with an authority prescription for sunitinib,

AND

Patient must have stable or responding disease according to the Response Evaluation Criteria In Solid Tumours (RECIST),

AND

The treatment must be the sole PBS-subsidised tyrosine kinase inhibitor therapy for this condition.

**Note**
Patients who have progressive disease with sunitinib are no longer eligible for PBS-subsidised sunitinib.

**Note**
Patients who have developed progressive disease on pazopanib are not eligible to receive PBS-subsidised sunitinib.

**Note**
Response Evaluation Criteria In Solid Tumours (RECIST) is defined as follows:

Complete response (CR) is disappearance of all target lesions.

Partial response (PR) is a 30% decrease in the sum of the longest diameter of target lesions.

Progressive disease (PD) is a 20% increase in the sum of the longest diameter of target lesions.

Stable disease (SD) is small changes that do not meet above criteria.

**Note**
Special Pricing Arrangements apply.

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**SUNITINIB**

**Authority required**

Initial PBS-subsidised treatment as monotherapy of a patient with WHO performance status of 2 or less with a metastatic or unresectable malignant gastrointestinal stromal tumour after failure of imatinib mesylate treatment due to resistance or intolerance.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Sunitinib Malate (Sutent) PBS Authority Application for Use in the Treatment of Gastrointestinal Stromal Tumour - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and

(3) a signed patient acknowledgement.

Patients who have failed to respond or are intolerant to imatinib are no longer eligible to receive PBS-subsidised imatinib

**Authority required**

Continuing PBS-subsidised treatment as monotherapy of a patient with WHO performance status of 2 or less with a metastatic or unresectable malignant gastrointestinal stromal tumour who has previously been issued with an authority prescription for sunitinib and who does not have progressive disease.
Applications for continuing treatment may be made by telephone (1800 700 270, hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Patients who have failed to respond or who are intolerant to imatinib are no longer eligible to receive PBS-subsidised imatinib.

Patients who have progressive disease on sunitinib are no longer eligible for PBS-subsidised sunitinib.

**Note**
Any queries concerning the arrangements to prescribe sunitinib malate may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Any queries concerning patients who are enrolled on the Sunitinib Compassionate Program may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authority to prescribe sunitinib malate should be forwarded to:
Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Sunitinib malate is not PBS-subsidised for the treatment of patients with resectable malignant gastrointestinal stromal tumours.

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

**Note**
Special Pricing Arrangements apply.

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**Other antineoplastic agents**

**HYDROXYUREA**
hydroxyurea 500 mg capsule, 100 1 .. .. 76.80 36.90 Hydrea BQ

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**ENDOCRINE THERAPY**

**HORMONES AND RELATED AGENTS**

**Progestogens**

**MEDROXYPROGESTERONE**

**Restricted benefit**
Hormone-dependent breast cancer

**Restricted benefit**
Endometrial cancer

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**MEDROXYPROGESTERONE**

**Restricted benefit**
Hormone-dependent advanced breast cancer

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**MEGESTROL**

**Restricted benefit**
Hormone-dependent advanced breast cancer

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<tr>
<td>3229</td>
<td>Locally advanced (equivalent to stage C) or metastatic (equivalent to stage D) carcinoma of the prostate</td>
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<tr>
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<td>1</td>
<td>..</td>
<td>1109.10</td>
<td>36.90</td>
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<tr>
<td><strong>GOSERELIN</strong> Authority required</td>
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<tr>
<td></td>
<td>Locally advanced (equivalent to stage C) or metastatic (equivalent to stage D) carcinoma of the prostate</td>
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<tr>
<td><strong>Authority required</strong> Hormone-dependent locally advanced (equivalent to stage III) or metastatic (equivalent to stage IV) breast cancer in pre-menopausal women</td>
<td></td>
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<tr>
<td><strong>Authority required</strong> Short-term treatment (up to 6 months) of visually proven endometriosis (only 1 course of not more than 6 months’ therapy will be authorised)</td>
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<tr>
<td><strong>Authority required</strong> Hormone-dependent breast cancer as an alternative to adjuvant chemotherapy in peri- or pre-menopausal women</td>
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<td>1454M</td>
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<td>5</td>
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<td>333.34</td>
<td>36.90</td>
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<tr>
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<tr>
<td>3239</td>
<td>Metastatic (equivalent to stage D) prostatic carcinoma in patients for whom a combination of an antiandrogen and a GnRH (LH-RH) agonist is required</td>
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<tr>
<td><strong>Note</strong></td>
<td>No applications for increased maximum quantities and/or repeats will be authorised.</td>
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<tr>
<td>9065D</td>
<td>goserelin 10.8 mg implant [1 implant] (&amp;) bicalutamide 50 mg tablet [28 tablets], 1 pack</td>
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<td>1248.63</td>
<td>36.90</td>
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<tr>
<td>9066E</td>
<td>goserelin 10.8 mg implant [1 implant] (&amp;) bicalutamide 50 mg tablet [84 tablets], 1 pack</td>
<td>‡1</td>
<td>1</td>
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<td>1527.71</td>
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<td>9064C</td>
<td>goserelin 3.6 mg implant [1 implant] (&amp;) bicalutamide 50 mg tablet [28 tablets], 1 pack</td>
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<td>Locally advanced (equivalent to stage C) or metastatic (equivalent to stage D) carcinoma of the prostate</td>
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<td>leuprorelin acetate 22.5 mg injection: modified release [1 syringe] (&amp;) inert substance diluent [1 syringe], 1 pack</td>
<td>1</td>
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<td>1109.10</td>
<td>36.90</td>
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<tr>
<td>8876E</td>
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<td>..</td>
<td>1109.10</td>
<td>36.90</td>
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<tr>
<td>8709J</td>
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<td>1</td>
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<td>1451.67</td>
<td>36.90</td>
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<tr>
<td>8877F</td>
<td>leuprorelin acetate 30 mg injection: modified release [1 x 30 mg syringe] (&amp;) inert substance diluent [1 x 2 mL syringe], 1 pack</td>
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<td>..</td>
<td>1451.67</td>
<td>36.90</td>
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<tr>
<td>8859G</td>
<td>leuprorelin acetate 45 mg injection: modified release [1 syringe] (&amp;) inert substance diluent [1 syringe], 1 pack</td>
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<td>..</td>
<td>..</td>
<td>2124.32</td>
<td>36.90</td>
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<tr>
<td>8707G</td>
<td>leuprorelin acetate 7.5 mg injection: modified release [1 syringe] (&amp;) inert substance diluent [1 syringe], 1 pack</td>
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<td>36.90</td>
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<td>8875D</td>
<td>leuprorelin acetate 7.5 mg injection: modified release [1 x 7.5 mg syringe] (&amp;) inert substance diluent [1 x 2 mL syringe], 1 pack</td>
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<td>..</td>
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<td></td>
<td>syringe], 1 pack</td>
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<td><strong>TRIPTORELIN</strong></td>
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<td>1</td>
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<td>36.90</td>
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<tr>
<td>5297T</td>
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<td>..</td>
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<td>36.90</td>
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<td>9378N</td>
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<td>5</td>
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<td>36.90</td>
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</tbody>
</table>

**HORMONE ANTAGONISTS AND RELATED AGENTS**

**Anti-estrogens**

**TAMOXIFEN**

**Restricted benefit**

Treatment of hormone-dependent breast cancer

**Note**

This drug is not PBS-subsidised for primary prevention of breast cancer.

**Note**

Shared Care Model:

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

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<th>Dispensed Price for Max. Qty $</th>
<th>Premium $</th>
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<th>Brand Name and Manufacturer</th>
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<tr>
<td>2109B</td>
<td>tamoxifen 10 mg tablet, 60</td>
<td>1</td>
<td>5</td>
<td>..</td>
<td>24.22</td>
<td>25.37</td>
<td>Genox 10 AF</td>
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</table>

**TAMOXIFEN**

**Restricted benefit**

Treatment of hormone-dependent breast cancer

**Note**

This drug is not PBS-subsidised for primary prevention of breast cancer.

**Note**

For item codes 2110C and 1880Y, pharmaceutical benefits that have the form tablet 20 mg (base) are equivalent for the purposes of substitution.

**Note**

Shared Care Model:

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

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<tr>
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<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>1880Y</td>
<td>tamoxifen 20 mg tablet, 30</td>
<td>2</td>
<td>5</td>
<td>*2.20</td>
<td>*39.22</td>
<td>36.90</td>
<td>Nolvadex-D AP</td>
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<tr>
<td>2110C</td>
<td>tamoxifen 20 mg tablet, 60</td>
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<td>5</td>
<td>..</td>
<td>37.03</td>
<td>36.90</td>
<td>Genox 20 AF</td>
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</table>

**TOREMIFENE**

**Restricted benefit**

Treatment of hormone-dependent metastatic breast cancer in post-menopausal patients

**Note**

This drug is not PBS-subsidised for primary prevention of breast cancer.

<table>
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<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
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<th>Maximum Recordable Value for Safety Net $</th>
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<tr>
<td>8216K</td>
<td>toremifene 60 mg tablet, 30</td>
<td>1</td>
<td>5</td>
<td>..</td>
<td>74.08</td>
<td>36.90</td>
<td>Fareston MK</td>
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**Anti-androgens**

**BICALUTAMIDE**

**Authority required (STREAMLINED)**

3674
### ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration</th>
<th>Max. Qty</th>
<th>No. of Rpts</th>
<th>Dispensed Price for Max. Qty</th>
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<th>Brand Name and Manufacturer</th>
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<tr>
<td>8094B NP</td>
<td>Bicalutamide 50 mg tablet. 28</td>
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<td>5</td>
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<td>131.68</td>
<td>36.90</td>
<td>APO-Bicalutamide TX</td>
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<td>1014</td>
<td>Advanced carcinoma of the prostate</td>
<td>1</td>
<td>5</td>
<td></td>
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<td>1404</td>
<td>To reduce drive in sexual deviations in males</td>
<td>1</td>
<td>5</td>
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<td>99.89</td>
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<td>Cyprotec 100 QA</td>
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<tr>
<td>1270W</td>
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<td>5</td>
<td>..</td>
<td>*100.83</td>
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<td>Androcur-100 BN</td>
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<tr>
<td>3674</td>
<td>Metastatic (equivalent to stage D) prostatic carcinoma in combination with GnRH (LH-RH) analogue therapy</td>
<td>1</td>
<td>5</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>3675</td>
<td>Locally advanced (equivalent to stage C) or metastatic (equivalent to stage D) prostatic carcinoma, in combination with GnRH (LH-RH) analogue therapy</td>
<td>1</td>
<td>5</td>
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**Note**

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

**Note**

Shared Care Model:

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

<table>
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<tr>
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<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>3300</td>
<td>Locally advanced (equivalent to stage C) or metastatic (equivalent to stage D) prostatic carcinoma, in conjunction with surgical orchidectomy</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Note</strong></td>
<td>Shared Care Model: For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.</td>
<td></td>
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</tr>
</tbody>
</table>

#### Aromatase inhibitors

**ANASTROZOLE**

**Restricted benefit**

Treatment of hormone-dependent breast cancer in post-menopausal women

**Note**

This drug is not PBS-subsidised for primary prevention of breast cancer. This drug is not PBS-subsidised for adjuvant hormonal treatment of early breast cancer extended beyond 5 years.

**Note**

Shared Care Model:

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

8131Y

<table>
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<td>8131Y</td>
<td>nilutamide 150 mg tablet, 30</td>
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<td>5</td>
<td></td>
<td></td>
<td></td>
<td>Anandron SW</td>
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</table>

#### EXEMESTANE

**Restricted benefit**

Metastatic (Stage IV) breast cancer

**Clinical criteria:**

The condition must be hormone receptor positive,

AND

The condition must be human epidermal growth factor receptor 2 (HER2) negative,

AND

Patient must be receiving PBS-subsidised everolimus concomitantly for this condition.

**Population criteria:**

Patient must be female,

AND

Patient must be post-menopausal.

10103R

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
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**Note**

Shared Care Model:

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

8179L

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<td>8179L</td>
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## ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

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<td>GQ</td>
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<tr>
<td>a</td>
<td>Exemestane Pfizer</td>
<td>FZ</td>
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</table>

### EXEMESTANE

**Restricted benefit**

Treatment of hormone-dependent advanced breast cancer in post-menopausal women with disease progression following treatment with tamoxifen citrate

**Restricted benefit**

Treatment of hormone-dependent early breast cancer in post-menopausal women following a minimum of 2 years' treatment with tamoxifen citrate

**Note**

This drug is not PBS-subsidised for primary prevention of breast cancer.

This drug is not PBS-subsidised for adjuvant hormonal treatment of early breast cancer extended beyond 5 years, i.e. a patient who has received 2 years of tamoxifen therapy may only receive 3 years of PBS-subsidised treatment with exemestane.

**Note**

Shared Care Model:

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

### LETROZOLE

**Restricted benefit**

Treatment of hormone-dependent advanced breast cancer in post-menopausal women

**Restricted benefit**

Treatment of hormone-dependent early breast cancer in post-menopausal women

**Restricted benefit**

Extended adjuvant treatment of hormone-dependent early breast cancer in post-menopausal women commencing within 6 months of ceasing treatment with tamoxifen citrate

**Note**

This drug is not PBS-subsidised for primary prevention of breast cancer.

This drug is not PBS-subsidised for adjuvant hormonal treatment of early breast cancer extended beyond 5 years.

This drug is not PBS-subsidised for extended adjuvant early breast cancer treatment where the total duration of letrozole (or any other aromatase inhibitor) treatment extends beyond 5 years.

**Note**

Shared Care Model:

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

**ABIRATERONE**

*Authority required*

Castration resistant metastatic carcinoma of the prostate

**Clinical criteria:**

AND

The treatment must not be used in combination with chemotherapy,

AND

Patient must have failed treatment with docetaxel due to resistance or intolerance,

AND

Patient must not receive PBS-subsidised abiraterone if progressive disease develops while on abiraterone.

**Note**

Patients who have received PBS-subsidised abiraterone or cabazitaxel are not eligible for PBS-subsidised docetaxel.

**Note**

Special Pricing Arrangements apply.

<table>
<thead>
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<th>Brand Name and Manufacturer</th>
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<td>3600.24</td>
<td>36.90</td>
<td>Zytiga</td>
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<td>TW</td>
</tr>
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</table>

**DEGARELIX**

*Authority required (STREAMLINED)*

Locally advanced (equivalent to stage C) or metastatic (equivalent to stage D) carcinoma of the prostate

**Note**

No applications for increased maximum quantities and/or repeats will be authorised for the 120 mg powder for injection.

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
<th>Dispensed Price for Max. Qty</th>
<th>Premium $</th>
<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
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<tr>
<td>2785N</td>
<td>degarelix 120 mg injection [2 x 120 mg vials] (&amp;) inert substance diluent [2 syringes], 1 pack</td>
<td>‡1</td>
<td>..</td>
<td>..</td>
<td>439.06</td>
<td>36.90</td>
<td>Firmagon 120mg FP</td>
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<tr>
<td>2784M</td>
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<td>5</td>
<td>..</td>
<td>420.54</td>
<td>36.90</td>
<td>Firmagon 80mg FP</td>
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</table>

**IMMUNOSTIMULANTS**

**Interferons**

**INTERFERON ALFA-2A**

*Authority required*

Hairy cell leukaemia

*Authority required*

Myeloproliferative disease with excessive thrombocytosis

**Caution**

Treatment with interferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored.

<table>
<thead>
<tr>
<th>Code</th>
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<th>Brand Name and Manufacturer</th>
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<td>8180M</td>
<td>interferon alfa-2a 3 million</td>
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<td>Roferon-A RO</td>
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<td>Max. Qty (Packs)</td>
<td>No. of Rpts</td>
<td>Premium $</td>
<td>Dispensed Price for Max. Qty $</td>
<td>Maximum Recordable Value for Safety Net $</td>
<td>Brand Name and Manufacturer</td>
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<tr>
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<td>8551C</td>
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<td>834B</td>
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<td>*606.37</td>
<td>36.90</td>
<td>Intron A Redipen</td>
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<td>8476D</td>
<td>interferon alfa-2b 30 million international units/1.2 mL injection, 1 x 1.2 mL cartridge</td>
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<td>36.90</td>
<td>Intron A Redipen</td>
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<td>8572E</td>
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<td>4</td>
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<td>*606.37</td>
<td>36.90</td>
<td>Intron A Redipen</td>
</tr>
<tr>
<td>8185E</td>
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<td>4</td>
<td>..</td>
<td>*606.37</td>
<td>36.90</td>
<td>Intron A Redipen</td>
</tr>
</tbody>
</table>

**INTERFERON ALFA-2A**

**Authority required**

Low grade non-Hodgkin’s lymphoma with clinical features suggestive of a poor prognosis, in combination with anthracycline-based chemotherapy

**Caution**

Treatment with interferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored.

**INTERFERON BETA-1A**

**Authority required**

Initial treatment of clinically definite relapsing-remitting multiple sclerosis in ambulatory (without assistance or support) patients who have...
experienced at least 2 documented attacks of neurological dysfunction, believed to be due to the multiple sclerosis, in the preceding 2 years. The diagnosis must be confirmed by magnetic resonance imaging of the brain and/or spinal cord and the date of the scan included in the authority application, unless the authority application is accompanied by written certification provided by a radiologist that an MRI scan is contraindicated because of the risk of physical (not psychological) injury to the patient. The authority will be limited to the maximum quantity and number of repeats indicated in the schedule

**Authority required**
Continuing treatment of clinically definite relapsing-remitting multiple sclerosis in patients previously issued with an authority prescription for this drug who do not show continuing progression of disability while on treatment with this drug and who have demonstrated compliance with, and an ability to tolerate, this therapy. Authorities will be limited to the maximum quantity and number of repeats indicated in the schedule

<table>
<thead>
<tr>
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<th>Maximum Recordable Value for Safety Net $</th>
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</thead>
<tbody>
<tr>
<td>8968B</td>
<td>Interferon Beta-1a Injection 44 micrograms (12,000,000 i.u.) in 0.5 mL single dose autoinjector, 12</td>
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<td>1057.11</td>
<td>36.90</td>
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<td>8289G</td>
<td>Interferon beta-1a 30 microgram (6 million international units) injection [4 x 30 microgram vials] (&amp;) inert substance diluent [4 x 1.1 mL syringes], 1 pack</td>
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<td>36.90</td>
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</table>

**INTERFERON BETA-1B**

**Authority required**
Initial treatment of clinically definite relapsing-remitting multiple sclerosis in ambulatory (without assistance or support) patients who have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to the multiple sclerosis, in the preceding 2 years. The diagnosis must be confirmed by magnetic resonance imaging of the brain and/or spinal cord and the date of the scan included in the authority application, unless the authority application is accompanied by written certification provided by a radiologist that an MRI scan is contraindicated because of the risk of physical (not psychological) injury to the patient. The authority will be limited to the maximum quantity and number of repeats indicated in the schedule

**Authority required**
Continuing treatment of clinically definite relapsing-remitting multiple sclerosis in patients previously issued with an authority prescription for this drug who do not show continuing progression of disability while on treatment with this drug and who have demonstrated compliance with, and an ability to tolerate, this therapy. Authorities will be limited to the maximum quantity and number of repeats indicated in the schedule

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<tr>
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<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>8101J</td>
<td>Interferon beta-1b 8 million international units (250 microgram) injection [15 x 250 microgram vials] (&amp;) inert substance diluent [15 x 1.2 mL syringes], 1 pack</td>
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<td>5</td>
<td>1001.15</td>
<td>36.90</td>
<td>a Betaferon BN</td>
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</tbody>
</table>

**Other immunostimulants**

**BACILLUS CALMETTE AND GUERIN-CONNAUGHT STRAIN**

**Restricted benefit**
Treatment of carcinoma in situ of the urinary bladder

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
<th>Dispensed Price for Max. Qty $</th>
<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
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<tr>
<td>1140B</td>
<td>Bacillus Calmette and Guerin-Connaught strain 660 million colony forming units injection [1 x 81 mg vial] (&amp;) inert substance diluent [1 x 3 mL vial], 1 pack</td>
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<td>1</td>
<td>460.21</td>
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<td>ImmuCyst SW</td>
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</table>

**BACILLUS CALMETTE AND GUERIN-TICE STRAIN**

**Restricted benefit**
Primary and relapsing superficial urothelial carcinoma of the bladder

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
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<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>1131M</td>
<td>Bacillus Calmette and Guerin-Tice strain 500 million colony forming units injection, 3 x 500 million colony forming units vials</td>
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<td>1</td>
<td>556.73</td>
<td>36.90</td>
<td>OncoTICE MK</td>
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**GLATIRAMER ACETATE**

**Authority required**
Initial treatment of clinically definite relapsing-remitting multiple sclerosis in ambulatory (without assistance or support) patients who have
Authority required

Continuing treatment of clinically definite relapsing-remitting multiple sclerosis in patients previously issued with an authority prescription for this drug who do not show continuing progression of disability while on treatment with this drug and who have demonstrated compliance with, and an ability to tolerate, this therapy. Authorities will be limited to the maximum quantity and number of repeats indicated in the schedule.

Selective immunosuppressants

ABATACEPT

Authority required

Initial PBS-subsidised treatment with abatacept, in combination with methotrexate at a dose of at least 7.5 mg weekly, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults who:

(a) have severe active rheumatoid arthritis; and

(b) have received no PBS-subsidised treatment with a bDMARD for this condition in the previous 24 months; and

(c) have failed, in the 24 months immediately prior to the date of application, to achieve an adequate response to at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs), which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be:

— hydroxychloroquine at a dose of at least 200 mg daily; or

— leflunomide at a dose of at least 10 mg daily; or

— sulfasalazine at a dose of at least 2 g daily.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, then the 6 months of intensive DMARD treatment must include at least 3 months continuous treatment with each of at least 2 of the DMARDs:

— hydroxychloroquine at a dose of at least 200 mg daily; and/or

— leflunomide at a dose of at least 10 mg daily; and/or

— sulfasalazine at a dose of at least 2 g daily.

The application must include details of the concomitant or intolerance to methotrexate. Details of the toxicities, including severity, which will be accepted for the purposes of a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose can be found on the Medicare Australia website [www.medicareaustralia.gov.au]. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

If 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved product information or cannot be tolerated at the doses specified above, then one or more of the following DMARDs may be used in place of these agents in order to satisfy the requirement for a trial of 6 months of intensive DMARD therapy with at least 2 DMARDs taken continuously for at least 3 months each:

— azathioprine at a dose of at least 1 mg/kg per day; and/or

— cyclosporin at a dose of at least 2 mg/kg/day; and/or

— sodium aurothiomalate at a dose of 50 mg weekly.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances. Details of the toxicities, including severity, which will be accepted as a reason for substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial can be found on the Medicare Australia website [www.medicareaustralia.gov.au].

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance and dose for each DMARD must be provided in the authority application. Details of the toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy can be found on the Medicare Australia website [www.medicareaustralia.gov.au].

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L.
AND either

(i) a total active joint count of at least 20 active (swollen and tender) joints; or

(ii) at least 4 active joints from the following list of major joints:
— elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
— shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

1. completed authority prescription form(s); and

2. a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and

3. a signed patient acknowledgement.

A maximum of 16 weeks of treatment will be authorised under this restriction.

Initial treatment with an I.V. loading dose: Two completed authority prescriptions must be submitted with the initial application. One prescription must be for the I.V. loading dose for sufficient vials for one dose based on the patient’s weight with no repeats. The second prescription must be written for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats.

Initial treatment with no loading dose: One completed authority prescription must be submitted with the initial application. The prescription must be written with a maximum quantity of 4 and up to 3 repeats. Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Assessment of a patient’s response to an initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with abatacept.

Patients who fail to demonstrate a response to treatment with abatacept under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition

**Authority required**

Initial 2 (change or re-commencement after break of less than 24 months)

Initial course of PBS-subsidised treatment with abatacept, in combination with methotrexate at a dose of at least 7.5 mg weekly, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults who:

(a) have a documented history of severe active rheumatoid arthritis; and

(b) have received prior PBS-subsidised bDMARD treatment for this condition and are eligible to receive further bDMARD therapy.

The authority application must be made in writing and must include:

1. completed authority prescription form(s); and

2. a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

Applications for patients who have received PBS-subsidised treatment with abatacept and who wish to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient’s most recent course of PBS-subsidised abatacept treatment, within the timeframes specified below.

A maximum of 16 weeks of treatment will be authorised under this restriction.

Initial treatment with an I.V. loading dose: Two completed authority prescriptions must be submitted with the initial application. One prescription must be for the I.V. loading dose for sufficient vials for one dose based on the patient’s weight with no repeats. The second prescription must be written for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats.

Initial treatment with no loading dose: One completed authority prescription must be submitted with the initial application. The prescription must be written with a maximum quantity of 4 and up to 3 repeats.

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Where the most recent course of PBS-subsidised abatacept treatment was approved under either of the initial 1 or 2 treatment restrictions, patients must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be provided to Medicare...
Where the most recent course of PBS-subsidised abatacept treatment was approved under the continuing treatment criteria, patients must have been assessed for response, and the assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Patients who fail to demonstrate a response to treatment with abatacept under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**Note**
Any queries concerning the arrangements to prescribe abatacept may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Further prescribing information (including Authority Application Forms) is on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe abatacept should be forwarded to:
Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

**Note**
TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying anti-rheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab) and the T-cell co-stimulation modulator (abatacept).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

PBS-subsidised abatacept, golimumab, infliximab and rituximab must be used in combination with methotrexate at a dose of at least 7.5 mg weekly. Where a patient cannot tolerate 7.5 mg of methotrexate weekly, they are eligible to receive PBS-subsidised adalimumab, certolizumab pegol, etanercept and tocilizumab.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:
- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact Medicare Australia on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD. (1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab and tocilizumab, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.
Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to Medicare Australia within 4 weeks.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:

Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient’s weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:

A further application may be submitted to Medicare Australia 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialed.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept patients:

Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

Note

(3) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and Medicare Australia will assess response according to these revised baseline measurements.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

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

**Note**
Special Pricing Arrangements apply.

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<tr>
<th>Code</th>
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<td>Orencia BQ</td>
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**ABATACEPT**

**Authority required**

Continuing treatment

Continuing PBS-subsidised treatment with abatacept, in combination with methotrexate at a dose of at least 7.5 mg weekly, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults:

(a) who have a documented history of severe active rheumatoid arthritis; and

(b) who have demonstrated an adequate response to treatment with abatacept; and

(c) whose most recent course of PBS-subsidised bDMARD treatment was with abatacept.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(i) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(ii) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

— elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

— shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

A maximum of 24 weeks of treatment will be approved under this restriction.

Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

All applications for continuing treatment with abatacept must include a measurement of response to the prior course of therapy. This assessment must be provided to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with abatacept, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

Patients who fail to demonstrate a response to treatment with abatacept under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**Note**
Any queries concerning the arrangements to prescribe abatacept may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Further prescribing information (including Authority Application Forms) is on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe abatacept should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826
Note

TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying anti-rheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alpha antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab) and the T-cell co-stimulation modulator (abatacept).

Patients are eligible for PBS-subsidised treatment with rituximab, etanercept and tocilizumab.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:
- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact Medicare Australia on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab and tocilizumab, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to Medicare Australia within 4 weeks.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:

Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient’s weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:

A further application may be submitted to Medicare Australia 24 weeks after the first infusion. New baselines may be submitted with this
application if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to re-qualify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept patients:

Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

Note (3) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and Medicare Australia will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

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

Note Special Pricing Arrangements apply.

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### ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

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<td>Maintenance therapy, following initiation and stabilisation of treatment with everolimus and where therapy remains under the supervision and direction of the transplant unit reviewing that patient, of patients with renal transplants. The name of the specialised transplant unit reviewing treatment and the date of the latest review at the specialised transplant unit must be included in the authority application.</td>
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<td>Authority required</td>
<td>Caution</td>
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**FINGOLIMOD**

**Authority required**

Initial treatment, as monotherapy, of clinically definite relapsing-remitting multiple sclerosis in an ambulatory (without assistance or support) patient who has experienced at least 2 documented attacks of neurological dysfunction, believed to be due to the multiple sclerosis, in the preceding 2 years. The diagnosis must be confirmed by magnetic resonance imaging of the brain and/or spinal cord and the date of the scan included in the authority application, unless the authority application is accompanied by written certification provided by a radiologist that an MRI scan is contraindicated because of the risk of physical (not psychological) injury to the patient. The authority will be limited to the maximum quantity and number of repeats indicated in the schedule.

**Authority required**

Continuing treatment, as monotherapy, of clinically definite relapsing-remitting multiple sclerosis in a patient previously issued with an authority prescription for this drug who does not show continuing progression of disability while on treatment with this drug and who has demonstrated compliance with, and an ability to tolerate, this therapy. Authorities will be limited to the maximum quantity and number of repeats indicated in the schedule.

**Note**

Special Pricing Arrangements apply.

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**LEFLUNOMIDE**

**Authority required (STREAMLINED)**

Treatment of severe active psoriatic arthritis where other disease modifying anti-rheumatic drugs (including methotrexate) are ineffective and/or inappropriate. Treatment must be initiated by a physician.

**Caution**

Leflunomide is a category X drug and must not be given to pregnant women. Pregnancy should be avoided for two years after cessation of therapy, unless special wash-out procedures are carried out.

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**LEFLUNOMIDE**

**Authority required (STREAMLINED)**

Treatment of severe active rheumatoid arthritis where other disease modifying anti-rheumatic drugs (including methotrexate) are ineffective and/or inappropriate. Treatment must be initiated by a physician.

**Caution**

Leflunomide is a category X drug and must not be given to pregnant women. Pregnancy should be avoided for two years after cessation of therapy, unless special wash-out procedures are carried out.

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### MYCOPHENOLATE

**Authority required**

WHO Class III, IV or V lupus nephritis

Treatment Phase: Maintenance

**Clinical criteria:**

The condition must be proven by biopsy,

AND

Patient must have received initiation treatment,

AND

The treatment must be under the supervision and direction of a nephrologist reviewing the patient.

The name of the nephrologist reviewing treatment and the date of the latest review, which must be within the last 12 months, must be included in the authority application.

**Caution**

Careful monitoring of patients is mandatory.

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### MYCOPHENOLATE

**Authority required**

Maintenance therapy, following initiation and stabilisation of treatment with mycophenolate sodium and where therapy remains under the supervision and direction of the transplant unit reviewing that patient, of patients with renal transplants. The name of the specialised transplant unit reviewing treatment and the date of the latest review at the specialised transplant unit must be included in the authority application.

**Caution**

Careful monitoring of patients is mandatory.

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### MYCOPHENOLATE

**Authority required**

Maintenance therapy, following initiation and stabilisation of treatment with mycophenolate mofetil and where therapy remains under the supervision and direction of the transplant unit reviewing that patient, of patients with renal transplants. The name of the specialised transplant unit reviewing treatment and the date of the latest review at the specialised transplant unit must be included in the authority application.

**Authority required**

Maintenance therapy, following initiation and stabilisation of treatment with mycophenolate mofetil and where therapy remains under the supervision and direction of the transplant unit reviewing that patient, of patients with cardiac transplants. The name of the specialised transplant unit reviewing treatment and the date of the latest review at the specialised transplant unit must be included in the authority application.

**Caution**

Careful monitoring of patients is mandatory.

**Note**

For item codes 8649F and 1836P, pharmaceutical benefits that have the form capsule 250 mg are equivalent for the purposes of substitution.

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### MYCOPHENOLATE

**Authority required**

Maintenance therapy, following initiation and stabilisation of treatment with mycophenolate mofetil and where therapy remains under the supervision and direction of the transplant unit reviewing that patient, of patients with renal transplants. The name of the specialised transplant unit reviewing treatment and the date of the latest review at the specialised transplant unit must be included in the authority application.

**Caution**

Careful monitoring of patients is mandatory.

### SIROLIMUS

**Authority required**

Maintenance therapy, following initiation and stabilisation of treatment with sirolimus and where therapy remains under the supervision and direction of the transplant unit reviewing that patient, of patients with renal transplants. The name of the specialised transplant unit reviewing treatment and the date of the latest review at the specialised transplant unit must be included in the authority application.

**Caution**

Careful monitoring of patients is mandatory.

### TERIFLUNOMIDE

**Authority required**

Multiple sclerosis

**Treatment Phase:** Initial treatment

**Clinical criteria:**

The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR

The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient, AND

The treatment must be as monotherapy, AND

Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to the multiple sclerosis, in the preceding 2 years; OR

Patient must have been receiving treatment with this drug prior to 1 December 2013, AND
Patient must be ambulatory (without assistance or support).

Where applicable, the date of the magnetic resonance imaging scan must be provided with the authority application.

**Authority required**

Multiple sclerosis

Treatment Phase: Continuing treatment

**Clinical criteria:**

The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR

The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient, AND

The treatment must be as monotherapy, AND

Patient must have previously been issued with an authority prescription for this drug, AND

Patient must not show continuing progression of disability while on treatment with this drug.

Where applicable, the date of the magnetic resonance imaging scan must be provided with the authority application.

**Caution**

Teriflunomide is a category X drug and must not be given to pregnant women or women of childbearing potential who are not currently using reliable contraception.

Pregnancy should be avoided for two years after cessation of therapy, unless special wash-out procedures are carried out.

**Note**

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

**Note**

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

**Note**

Special Pricing Arrangements apply.

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**Tumor necrosis factor alpha (TNF-) inhibitors**

**ADALIMUMAB**

**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months)

**Clinical criteria:**

Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years, AND

Patient must have received no PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition in the previous 24 months; OR

Patient must have received no PBS-subsidised bDMARD treatment for at least 5 years if they failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) in their last treatment cycle, AND

Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR

Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR

Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR

Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR

Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6
months of intensive treatment with DMARDs which, if 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above, must include at least 3 months continuous treatment with each of at least 2 DMARDs, with one or more of the following DMARDs being used in place of the DMARDs which are contraindicated or not tolerated: (i) azathioprine at a dose of at least 1 mg/kg per day; and/or (ii) cyclosporin at a dose of at least 2 mg/kg/day; and/or (iii) sodium aurothiomalate at a dose of 50 mg weekly.

AND

Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.

If methotrexate is contraindicated according to the TGA-approved Product Information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance and dose for each DMARD must be provided in the authority application.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

(a) an active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form; and

(3) a signed patient acknowledgement.

If a patient fails to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle. A patient may re-trial adalimumab after a minimum of 5 years have elapsed between the date of the last approval for PBS-subsidised bDMARD therapy in the last treatment cycle and the date of the first application under a new treatment cycle.

Note

The Department of Human Services website (www.humanservices.gov.au) has details of the toxicities, including severity, which will be accepted for
the following purposes:

(a) exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose;

(b) substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial;

(c) exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy.

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

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

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

Note
TREATMENT OF ADULT PATIENTS WITH A HISTORY OF JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient over 18 years who has a history of juvenile idiopathic arthritis with onset prior to the age of 18 years. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.

From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 5 year break in PBS-subsidised bDMARD therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date of the last approval for PBS-subsidised bDMARD therapy in the last treatment cycle to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 24 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 24 months may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 24 months must commence a new treatment cycle. The length of the break in therapy is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or

(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or

(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have
failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

A patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count and ESR/CRP) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.

(4) Re-commencement of treatment after a 24 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 24 months, must requalify for treatment under the Initial 1 treatment restriction.

**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after break of less than 24 months)

Clinical criteria:

Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years,

AND

Patient must have received prior PBS-subsidised treatment with adalimumab, etanercept or tocilizumab for this condition in this treatment cycle,

AND

Patient must not have failed PBS-subsidised therapy with adalimumab for this condition in the current treatment cycle,

AND

Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

For the purposes of this restriction ‘biological disease modifying anti-rheumatic drug’ and ‘bDMARD’ mean adalimumab, etanercept or tocilizumab.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and
Applications for a patient who has received PBS-subsidised treatment with adalimumab in this treatment cycle and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient’s most recent course of PBS-subsidised adalimumab treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised adalimumab treatment was approved under either of the Initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised adalimumab treatment was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with adalimumab.

If a patient fails to respond to PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following:

(a) an active joint count of fewer than 10 active (swollen and tender) joints; or
(b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or
(c) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

TREATMENT OF ADULT PATIENTS WITH A HISTORY OF JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient over 18 years who has a history of juvenile idiopathic arthritis with onset prior to the age of 18 years. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.

From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and
(ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 5 year break in PBS-subsidised bDMARD therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date of the last approval for PBS-subsidised bDMARD therapy in the last treatment cycle to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 24 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 24 months may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 24 months must commence a new treatment cycle. The length of the break in therapy is measured from the date the most recent treatment with PBS-subsidised
bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle. There is no limit to the number of treatment cycles a patient may undertake.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

A patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count and ESR/CRP) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.

(4) Re-commencement of treatment after a 24 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 24 months, must requalify for treatment under the Initial 1 treatment restriction.

**Authority required**

Severe active juvenile idiopathic arthritis  
Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months) or Initial 2 (change or recommencement of treatment after break of less than 24 months) – balance of supply  

**Clinical criteria:**

Patient must have received insufficient adalimumab therapy under the Initial 1 (new patient or patient recommencing treatment after break of more than 24 months) restriction to complete 16 weeks treatment; OR  

Patient must have received insufficient adalimumab therapy under the Initial 2 (change or recommencement of treatment after break of less than 24 months) restriction to complete 16 weeks treatment.
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<th>Code</th>
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</table>

**ADALIMUMAB**

**Authority required**

Severe active juvenile idiopathic arthritis

**Treatment Phase:** Continuing treatment

**Clinical criteria:**

Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years,

AND

Patient must have demonstrated an adequate response to treatment with adalimumab,

AND

Patient must have received adalimumab as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment in this treatment cycle,

AND

Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

**Population criteria:**

Patient must be aged 18 years or older.

**Treatment criteria:**

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) an active joint count of fewer than 10 active (swollen and tender) joints; or
(b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or
(c) a reduction in the number of the following active joints, from at least 4, by at least 50%:
   (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
   (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used.
The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

All applications for continuing treatment with adalimumab must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with adalimumab, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with adalimumab.

If a patient fails to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle.

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Note
TREATMENT OF ADULT PATIENTS WITH A HISTORY OF JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient over 18 years who has a history of juvenile idiopathic arthritis with onset prior to the age of 18 years. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.

From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and must have, at a minimum, a 5 year break in PBS-subsidised bDMARD therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date of the last approval for PBS-subsidised bDMARD therapy in the last treatment cycle to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 24 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 24 months may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 24 months must commence a new treatment cycle. The length of the break in therapy is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or

(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of Initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

A patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised treatment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count and ESR/CRP) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD and that drug providing they have demonstrated an adequate response to treatment with that bDMARD.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.

(4) Re-commencement of treatment after a 24 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 24 months, must requalify for treatment under the initial 1 treatment restriction.

Authority required
Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment – balance of supply

Clinical criteria:
Patient must have received insufficient adalimumab therapy under the Continuing treatment restriction to complete 24 weeks treatment,

AND

The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

Treatment criteria:
Must be treated by a rheumatologist; OR
Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Note
Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

(a) has confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician as specified in the NOTE below; and

(b) has an externally draining enterocutaneous or rectovaginal fistula; and

(c) has signed a patient acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criteria for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

Authority applications must be made in writing and must include:

(a) two completed authority prescription forms; and

(b) a completed Fistulising Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) a completed current Fistula Assessment Form including the date of assessment of the patient’s condition; and

(ii) a signed patient acknowledgement.

The most recent fistula assessment must be no more than 1 month old at the time of application.

A maximum of 16 weeks treatment will be authorised under this criterion.

Two completed authority prescriptions must be submitted with every initial application for adalimumab. One prescription must be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats. The second prescription must be written for 2 doses of 40 mg and 2 repeats. Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with adalimumab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

An assessment of the patient’s response to this initial course of treatment must be made following a minimum of 12 weeks of therapy so that there is adequate time for a response to be demonstrated.

This assessment must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with adalimumab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised adalimumab treatment

Authority required

Initial 2

Change or re-commencement of treatment of complex refractory FISTULISING CROHN DISEASE.

Initial PBS-subsidised treatment with adalimumab by a gastroenterologist or a consultant physician as specified in the NOTE below, of a patient with complex refractory fistulising Crohn disease who:

(a) has a documented history of complex refractory fistulising Crohn disease; and

(b) in this treatment cycle, has received prior PBS-subsidised treatment with adalimumab or infliximab for a draining enterocutaneous or rectovaginal fistula; and

(c) has not failed PBS-subsidised therapy with adalimumab for this condition more than once in the current treatment cycle.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of TNF-alfa antagonist therapy within the time frames specified in the relevant restriction.

Where the most recent course of PBS-subsidised TNF-alfa antagonist treatment was approved under an initial treatment restriction, the patient must have been assessed for response to that course following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and this assessment must be submitted to Medicare Australia no later than 4 weeks from the
Once a patient has, at a minimum, a 5-year break in PBS-subsidised TNF-alfa antagonist therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised TNF-alfa antagonist treatment in the most recent cycle to the date of the date that course was ceased.

If the response assessment to the previous course of TNF-alfa antagonist treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of TNF-alfa antagonist.

Authority applications must be made in writing and must include:

(a) two completed authority prescription forms; and

(b) a completed Fistulising Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) a completed current Fistula Assessment Form including the date of assessment of the patient’s condition; and
details of prior TNF-alfa antagonist treatment including details of date and duration of treatment.

The most recent fistula assessment must be no more than 1 month old at the time of application.

A maximum of 16 weeks treatment will be authorised under this criterion.

Two completed authority prescriptions must be submitted with every initial application for adalimumab. One prescription must be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats. The second prescription must be written for 2 doses of 40 mg and 2 repeats. Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with adalimumab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

An assessment of the patient’s response to this initial course of treatment must be made following a minimum of 12 weeks of therapy so that there is adequate time for a response to be demonstrated.

This assessment must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with adalimumab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised adalimumab treatment

**Note**

Any queries concerning the arrangements to prescribe adalimumab may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe adalimumab should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

**Note**

**TREATMENT OF COMPLEX REFRACTORY FISTULISING CROHN DISEASE**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab and infliximab for patients with complex refractory fistulising Crohn disease. Where the term 'tumour necrosis factor (TNF) alfa antagonist' appears in the following NOTES and restrictions, it refers to adalimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 2 TNF-alfa antagonists at any 1 time.

From 1 April 2011, under the PBS, all patients will be able to commence a treatment cycle where they may try each PBS-subsidised TNF-alfa antagonist without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a TNF-alfa antagonist while they continue to show a response to therapy.

A patient who received PBS-subsidised TNF-alfa antagonist treatment prior to 1 April 2011 is considered to be in their first cycle as of 1 April 2011. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised TNF-alfa antagonist more than twice.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised TNF-alfa antagonist therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised TNF-alfa antagonist treatment in the most recent cycle to the date of the first application for initial treatment with a TNF-alfa antagonist under the new treatment cycle.

A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised TNF-alfa antagonist therapy after 1 April 2011.
To avoid confusion, an application for a patient who wishes to swap to the alternate TNF-alfa antagonist should be accompanied by the approved
are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

(i) a patient has received no prior PBS-subsidised TNF-alfa antagonist treatment in this treatment cycle and wishes to commence such therapy
(Initial 1); or
(ii) a patient has received prior PBS-subsidised (initial or continuing) TNF-alfa antagonist therapy and wishes to trial an alternate agent (Initial 2)
[further details are under ‘Swapping therapy’ below]; or
(iii) a patient wishes to re-commence treatment with a specific TNF-alfa antagonist following a break in PBS-subsidised therapy with that agent
(Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks of therapy for infliximab.
From 1 April 2011, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of
therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be
submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

For second and subsequent courses of PBS-subsidised TNF-alfa antagonist treatment, it is recommended that a patient is reviewed in the month
prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the
patient completing their current treatment course.

Adalimumab only: Two completed authority prescriptions must be submitted with every initial application for adalimumab. One prescription must
be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats. The second prescription must be written for 2 doses of 40 mg
and 2 repeats.

(b) Continuing treatment.
Following the completion of an initial treatment course with a specific TNF-alfa antagonist, a patient may qualify to receive up to 24 weeks of
continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive
continuing TNF-alfa antagonist treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted TNF-alfa
antagonist supply.
Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that
course was ceased.
Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised TNF-alfa antagonist is approved, a patient may swap if eligible to the alternate TNF-alfa
antagonist within the same treatment cycle.
A patient may trial the alternate TNF-alfa antagonist at any time, regardless of whether they are receiving therapy (initial or continuing) with a TNF-
alfa antagonist at the time of the application. However, they cannot swap to a particular TNF-alfa antagonist if they have failed to respond to prior
treatment with that drug two times within the same treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they
are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
To avoid confusion, an application for a patient who wishes to swap to the alternate TNF-alfa antagonist should be accompanied by the approved
authority prescription or remaining repeats for the TNF-alfa antagonist the patient is ceasing.

(3) Baseline measurements to determine response.
Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements submitted with
the first authority application for a TNF-alfa antagonist. However, prescribers may provide new baseline measurements any time that an initial
treatment authority application is submitted within a treatment cycle and Medicare Australia will assess response according to these revised
baseline measurements.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised TNF-alfa antagonist therapy of at least 5
years, must requalify for initial treatment with respect to the indices of disease severity.
(5) Patients ‘grandfathered’ onto PBS-subsidised treatment with adalumumab or infliximab.
A patient who commenced treatment with adalumumab for complex refractory fistulising Crohn disease prior to 4 November 2010 or infliximab
prior to 1 March 2010 and who continues to receive treatment at the time of application, may qualify for treatment under the initial ‘grandfather’
treatment restriction.
A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with adalumumab or
infliximab will be authorised under this criterion.
Following completion of the initial PBS-subsidised course, further applications for treatment with adalumumab or infliximab will be assessed under
the continuing treatment restriction.
‘Grandfather’ arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a ‘grandfather’ patient must
requalify for initial treatment under the criteria that apply to a new patient. See ‘Re-commencement of treatment after a 5-year break in PBS-
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**ADALIMUMAB**

**Authority required**

Initial 3 (grandfather)

Initial PBS-subsidised treatment of complex refractory FISTULISING CROHN DISEASE in a patient who has previously received non-PBS-subsidised therapy with adalimumab.

Initial PBS-subsidised supply for continuing treatment with adalimumab by a gastroenterologist, a consultant physician as specified in the NOTE below, or other consultant physician in consultation with a gastroenterologist of a patient who satisfies the following criteria:

(a) has a documented history of complex refractory fistulising Crohn disease and was receiving treatment with adalimumab prior to 4 November 2010; and

(b) had a draining enterocutaneous or rectovaginal fistula(e) prior to commencing treatment with adalimumab; and

(c) has signed a patient acknowledgement indicating that they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criteria for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and

(d) is receiving treatment with adalimumab at the time of application; and

(e) has demonstrated or sustained an adequate response to treatment with adalimumab.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

An adequate response to adalimumab treatment is defined as:

(a) a decrease from baseline in the number of open draining fistulae of greater than or equal to 50%; and/or

(b) a marked reduction in drainage of all fistula(e) from baseline, together with less pain and induration as reported by the patient.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Fistulising Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) a completed current and baseline Fistula Assessment form including the date of assessment of the patient's condition; and

(ii) a signed patient acknowledgement.

The current fistula assessment must be no more than 1 month old at the time of application.

The baseline fistula assessment must be from immediately prior to commencing treatment with adalimumab.

An assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criteria.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with adalimumab.

A maximum of 24 weeks treatment will be approved under this criterion.

Where fewer than 5 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Patients may qualify for PBS-subsidised treatment under this restriction once only

**Authority required**

Continuing treatment of complex refractory FISTULISING CROHN DISEASE.

Continuing PBS-subsidised treatment with adalimumab by a gastroenterologist, a consultant physician as specified in the NOTE below or other consultant physician in consultation with a gastroenterologist, of a patient who:

(a) has a documented history of complex refractory fistulising Crohn disease; and

(b) has demonstrated or sustained an adequate response to treatment with adalimumab.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or
consultant physicians [general medicine specialising in gastroenterology (code 82)].

An adequate response is defined as:

(a) a decrease from baseline in the number of open draining fistulae of greater than or equal to 50%; and/or
(b) a marked reduction in drainage of all fistula(e) from baseline, together with less pain and induration as reported by the patient.

Authority applications must be made in writing and must include:

(a) a completed authority prescription form; and
(b) a completed Fistulising Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes a completed Fistula Assessment form including the date of the assessment of the patient’s condition.

The fistula assessment must be no more than 1 month old at the time of application.

If the application is the first application for continuing treatment with adalimumab, an assessment of the patient’s response must be made following a minimum of 12 weeks after the first dose so that there is adequate time for a response to be demonstrated.

An assessment of the patient’s response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criteria.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with adalimumab.

Patients are eligible for receiving continuing adalimumab treatment in courses of up to 24 weeks providing they continue to sustain the response.

A maximum of 24 weeks treatment will be authorised under this criterion.

Where fewer than 5 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday)

**Note**

Any queries concerning the arrangements to prescribe adalimumab may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe adalimumab should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

**Note**

**TREATMENT OF COMPLEX RECURRENT FISTULISING CROHN DISEASE**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab and infliximab for patients with complex refractory fistulising Crohn disease. Where the term ‘tumour necrosis factor (TNF) alfa antagonist’ appears in the following NOTES and restrictions, it refers to adalimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 2 TNF-alfa antagonists at any 1 time.

From 1 April 2011, under the PBS, all patients will be able to commence a treatment cycle where they may trial each PBS-subsidised TNF-alfa antagonist without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a TNF-alfa antagonist while they continue to show a response to therapy.

A patient who received PBS-subsidised TNF-alfa antagonist treatment prior to 1 April 2011 is considered to be in their first cycle as of 1 April 2011. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised TNF-alfa antagonist more than twice.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised TNF-alfa antagonist therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised TNF-alfa antagonist treatment in the most recent cycle to the date of the first application for initial treatment with a TNF-alfa antagonist under the new treatment cycle.

A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised TNF-alfa antagonist therapy after 1 April 2011.

(a) Initial treatment.

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**Table: ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS**

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
<th>Premium $</th>
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<th>Maximum Recordable Value for Safety Net $</th>
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Antineoplastic and Immunomodulating Agents

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised TNF-alfa antagonist treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) TNF-alfa antagonist therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or

(iii) a patient wishes to re-commence treatment with a specific TNF-alfa antagonist following a break in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks of therapy for infliximab. From 1 April 2011, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist. For second and subsequent courses of PBS-subsidised TNF-alfa antagonist treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Adalimumab only: Two completed authority prescriptions must be submitted with every initial application for adalimumab. One prescription must be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats. The second prescription must be written for 2 doses of 40 mg and 2 repeats.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific TNF-alfa antagonist, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing TNF-alfa antagonist treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted TNF-alfa antagonist supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised TNF-alfa antagonist is approved, a patient may swap if eligible to the alternate TNF-alfa antagonist within the same treatment cycle.

A patient may trial the alternate TNF-alfa antagonist at any time, regardless of whether they are receiving therapy (initial or continuing) with a TNF-alfa antagonist at the time of the application. However, they cannot swap to a particular TNF-alfa antagonist if they have failed to respond to prior treatment with that drug two times within the same treatment cycle. To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to the alternate TNF-alfa antagonist should be accompanied by the approved authority prescription or remaining repeats for the TNF-alfa antagonist the patient is ceasing.

(3) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements submitted with the first authority application for a TNF-alfa antagonist. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and Medicare Australia will assess response according to these revised baseline measurements.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised TNF-alfa antagonist therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity.

(5) Patients ‘grandfathered’ onto PBS-subsidised treatment with adalimumab or infliximab.

A patient who commenced treatment with adalimumab for complex refractory fistulising Crohn disease prior to 4 November 2010 or infliximab prior to 1 March 2010 and who continues to receive treatment at the time of application, may qualify for treatment under the initial ‘grandfather’ treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with adalimumab or infliximab will be authorised under this criterion.

Following completion of the initial PBS-subsidised course, further applications for treatment with adalimumab or infliximab will be assessed under the continuing treatment restriction.

‘Grandfather’ arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a ‘grandfather’ patient must requalify for initial treatment under the criteria that apply to a new patient. See ‘Re-commencement of treatment after a 5-year break in PBS-subsidised therapy’ above for further details.
ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

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<td>..</td>
<td>1774.70</td>
<td>36.90</td>
<td>Humira VE</td>
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</tbody>
</table>

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

**ADALIMUMAB**

**Authority required**
Initial 1 (new patient or patient re-commencing after a break of more than 24 months)

Initial PBS-subsidised treatment with adalimumab, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults who:

(a) have severe active rheumatoid arthritis; and
(b) have received no PBS-subsidised treatment with a bDMARD for this condition in the previous 24 months; and
(c) have failed, in the 24 months immediately prior to the date of application, to achieve an adequate response to at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs), which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be:
   — hydroxychloroquine at a dose of at least 200 mg daily; or
   — leflunomide at a dose of at least 10 mg daily; or
   — sulfasalazine at a dose of at least 2 g daily.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, then the 6 months of intensive DMARD treatment must include at least 3 months continuous treatment with each of at least 2 of the DMARDs:
   — hydroxychloroquine at a dose of at least 200 mg daily; and/or
   — leflunomide at a dose of at least 10 mg daily; and/or
   — sulfasalazine at a dose of at least 2 g daily.

The application must include details of the contraindication or intolerance to methotrexate. Details of the toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose can be found on the Medicare Australia website [www.medicareaustralia.gov.au]. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

If 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved product information or cannot be tolerated at the doses specified above, then one or more of the following DMARDs may be used in place of these agents in order to satisfy the requirement for a trial of 6 months of intensive DMARD therapy with at least 2 DMARDs taken continuously for at least 3 months each:
   — azathioprine at a dose of at least 1 mg/kg per day; and/or
   — cyclosporin at a dose of at least 2 mg/kg/day; and/or
   — sodium aurothiomalate at a dose of 50 mg weekly.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances. Details of the toxicities, including severity, which will be accepted as a reason for substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial can be found on the Medicare Australia website [www.medicareaustralia.gov.au].

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance and dose for each DMARD must be provided in the authority application. Details of the toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy can be found on the Medicare Australia website [www.medicareaustralia.gov.au].

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

- an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either
  - (i) a total active joint count of at least 20 active (swollen and tender) joints; or
  - (ii) at least 4 active joints from the following list of major joints:
    - shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.
Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum timeframes specified below.

patients must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with adalimumab.

Patients who fail to demonstrate a response to treatment with adalimumab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition

Authority required

Initial 2 (change or re-commencement after break of less than 24 months)

Initial course of PBS-subsidised treatment with adalimumab, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults who:

(a) have a documented history of severe active rheumatoid arthritis; and

(b) have received prior PBS-subsidised bDMARD treatment for this condition and are eligible to receive further bDMARD therapy.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and

(3) a signed patient acknowledgement.

A maximum of 16 weeks of treatment will be authorised under this restriction.

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Assessment of a patient’s response to an initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with adalimumab.

Patients who fail to demonstrate a response to treatment with adalimumab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition

Note

TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying anti-rheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alpha antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab) and the T-cell co-stimulation modulator (abatacept).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time. PBS-subsidised abatacept, golimumab, infliximab and rituximab must be used in combination with methotrexate at a dose of at least 7.5 mg weekly. Where a patient cannot tolerate 7.5 mg of methotrexate weekly, they are eligible to receive PBS-subsidised adalimumab, certolizumab pegol, etanercept and tocilizumab.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alpha antagonist.
A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:

— a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,

— a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and

— once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact Medicare Australia on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or

(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or

(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or

(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab and tocilizumab, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to Medicare Australia within 4 weeks.

A response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:

Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials based on the patient’s weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:

A further application may be submitted to Medicare Australia 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

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Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate [ESR], the C-reactive protein [CRP] levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However, the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept patients:

Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

Note

(3) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and Medicare Australia will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Note

Any queries concerning the arrangements to prescribe adalimumab may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe adalimumab should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Note

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

Applications for treatment with adalimumab where the dosing frequency exceeds 40 mg per fortnight will not be approved.

Note

Special Pricing Arrangements apply.
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying anti-rheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab) and the T-cell co-stimulation modulator (abatacept).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised abatacept, golimumab, infliximab and rituximab must be used in combination with methotrexate at a dose of at least 7.5 mg weekly. Where a patient cannot tolerate 7.5 mg of methotrexate weekly, they are eligible to receive PBS-subsidised adalimumab, certolizumab pegol, etanercept and tocilizumab.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:

- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact Medicare Australia on 1800 700 270.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact Medicare Australia on 1800 700 270.
A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) agent.

A further application may be submitted to Medicare Australia 24 weeks after the first infusion. New baselines may be submitted with this application. Rituximab patients:

repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no deprivation.

Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with that agent (Initial 2).

Abatacept patients:

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that bDMARD. Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD. For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:

Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient’s weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:

A further application may be submitted to Medicare Australia 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment. Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased. Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction. Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy. Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate [ESR], the C-reactive protein [CRP] levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent. A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept patients:

Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.
In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

**Note**

(3) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and Medicare Australia will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

**Note**

Any queries concerning the arrangements to prescribe adalimumab may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au. Written applications for authority to prescribe adalimumab should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

**Note**

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

Applications for treatment with adalimumab where the dosing frequency exceeds 40 mg per fortnight will not be approved.

**Note**

Special Pricing Arrangements apply.

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<th>Code</th>
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<th>Max. Qty (Packs)</th>
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<td>1774.70</td>
<td>36.90</td>
<td>Humira VE</td>
</tr>
</tbody>
</table>

**ADALIMUMAB**

**Authority required**

Initial 1

Initial PBS-subsidised treatment with adalimumab, by a rheumatologist or clinical immunologist with expertise in the management of psoriatic arthritis, of adults who:

1. have severe active psoriatic arthritis; and
2. have received no prior PBS-subsidised biological treatment for this condition in this Treatment Cycle; and
3. have failed to achieve an adequate response to:
   a. methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months; and
   b. sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; or
   c. leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months.
If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity to necessitate permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of acceptable toxicities, including severity, can be found on the Medicare Australia website (www.medicareaustralia.gov.au).

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

- An elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either
  - (i) an active joint count of at least 20 active (swollen and tender) joints; or
  - (ii) at least 4 active joints from the following list of major joints:
    - elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
    - shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:

1. A completed authority prescription form; and
2. A completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and
3. A signed patient acknowledgement.

A maximum of 16 weeks treatment will be authorised under this restriction.

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

The assessment of the patient’s response to the initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Patients who fail to demonstrate a response to treatment with adalimumab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug, in this Treatment Cycle. Patients may re-trial adalimumab after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

**Authority required**

**Initial 2**

Initial PBS-subsidised treatment with adalimumab, by a rheumatologist or clinical immunologist with expertise in the management of psoriatic arthritis, of adults who:

1. Have a documented history of severe active psoriatic arthritis; and
2. Have received prior PBS-subsidised biological treatment for this condition in this Treatment Cycle and are eligible to receive further biological therapy; and
3. Have not failed treatment with adalimumab during the current Treatment Cycle.

Applications for patients who have received PBS-subsidised treatment with adalimumab within this Treatment Cycle and who wish to re-commence therapy with this drug within this same Cycle, must be accompanied by evidence of a response to the patient’s most recent course of PBS-subsidised adalimumab treatment, within the timeframes specified below.

A maximum of 16 weeks treatment will be authorised under this restriction.

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Where the most recent course of PBS-subsidised adalimumab treatment was approved under either of the initial treatment restrictions (i.e. for patients with no prior PBS-subsidised biological therapy or, under this restriction, for patients who have received previous PBS-subsidised biological therapy), patients must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be provided to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised adalimumab treatment was approved under the continuing treatment criteria, patients must have been assessed for response, and the assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

The authority application must be made in writing and must include:

1. A completed authority prescription form; and
2. A completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].
Patients who fail to demonstrate a response to treatment with adalimumab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug, in this Treatment Cycle. Patients may re-try adalimumab after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

**Note**

Any queries concerning the arrangements to prescribe adalimumab may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe adalimumab should be forwarded to:

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GPO Box 9826

HOBART TAS 7001

**Note**

TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents (adalimumab, etanercept, golimumab and infliximab) for adult patients with severe active psoriatic arthritis.

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological agents at any 1 time. Where the term ‘biological agents’ appears in the following notes and restrictions, it only refers to adalimumab, etanercept, golimumab and infliximab.

From 1 August 2006, all patients will be able to commence a ‘Biological Treatment Cycle’ (Cycle), where they may trial biological agents without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

Following demonstration of response to initial treatment, these biological agents are available under the PBS for continuing treatment as set out in the continuing treatment restriction for each agent.

Once patients have either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological therapy before they are eligible to commence another Cycle [further details are under (5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy’ below].

The 5-year break in therapy will be measured from the date the last approval for PBS-subsidised treatment was granted in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Cycle.

Within the same Cycle, patients are not allowed to fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for any biological agent, they must change to an alternate agent which they have not previously failed, if they wish to continue PBS-subsidised biological treatment.

Patients for whom a break in PBS-subsidised therapy of less than 5 years has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle.

There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe active psoriatic arthritis after 1 August 2010.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); and

(ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; and

(iii) patients wish to re-commence treatment with a specific biological agent following a break in PBS-subsidised therapy with that specific agent (Initial 2).

All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of therapy for all agents except for infliximab, for which a maximum of 22 weeks will be authorised. It is recommended that patients be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological agent supply.

Patients must be assessed for response to any course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

Grandfather patients — golimumab only.

Applications for patients who commenced treatment with golimumab prior to 1 March 2010 may apply for initial PBS-subsidised treatment as continuing therapy under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with any biological agent prior to PBS listing of that agent.

Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment for all agents.
Approval will be based on the criteria included in the relevant restriction.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological agent, patients may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. Patients are eligible to receive continuing biological treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

Patients must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

(3) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate biological agent without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements.

Patients may swap to an alternate biological agent at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological agent at the time of the application or not.

Patients may alternate between therapy with any biological agent of their choice (1 at a time) providing:

(i) they have not received PBS-subsidised treatment with that particular biological agent previously; or
(ii) they have demonstrated an adequate response to that particular biological agent if they have previously trialled it on the PBS; or
(iii) they have not previously failed to respond to treatment 3 times in this Treatment Cycle.

To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the biological agent the patient is ceasing.

(4) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the indices of disease severity submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment authority is submitted within a treatment cycle and Medicare Australia will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

Patients who wish to trial a second or subsequent treatment Cycle following a break in PBS-subsidised biological therapy of at least 5 years, must re-qualify for initial treatment with respect to both the indices of disease severity. Patients must have received treatment with methotrexate and sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured.

Note

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

Applications for treatment with adalimumab where the dosing frequency exceeds 40 mg per fortnight will not be approved.

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<th>Code</th>
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<th>No. of Rpts</th>
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</tr>
</tbody>
</table>

**ADALIMUMAB**

**Authority required**

Continuing treatment

Continuing PBS-subsidised treatment with adalimumab, by a rheumatologist or clinical immunologist with expertise in the management of psoriatic arthritis, of adults:

(1) who have a documented history of severe active psoriatic arthritis; and
(2) whose most recent course of PBS-subsidised biological agent for this condition in the current Treatment Cycle was with adalimumab; and
(3) who, at the time of application, demonstrate an adequate response to treatment with adalimumab.

An adequate response to treatment with adalimumab is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following:

(i) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
(ii) a reduction in the number of the following major active joints, from at least 4, by at least 50%:
### TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents (adalimumab, etanercept, golimumab and infliximab) for adult patients with severe active psoriatic arthritis.

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological agents at any 1 time. Where the term 'biological agents' appears in the following NOTES and restrictions, it only refers to adalimumab, etanercept, golimumab and infliximab.

From 1 August 2006, all patients will be able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

Following demonstration of response to initial treatment, these biological agents are available under the PBS for continuing treatment as set out in the continuing treatment restriction for each agent.

Once patients have either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological therapy before they are eligible to commence another Cycle [further details are under '(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' below].

The 5-year break in therapy will be measured from the date the last approval for PBS-subsidised treatment was granted in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Cycle.

Within the same Cycle, patients are not allowed to fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for any biological agent, they must change to an alternate agent which they have not previously failed, if they wish to continue PBS-subsidised biological treatment.

Patients for whom a break in PBS-subsidised therapy of less than 5 years has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.

There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe active psoriatic arthritis after 1 August 2010.

(1) Initial treatment.

Applications for initial treatment should be made where:

1. Patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); and
2. Patients who fail to demonstrate a response to treatment with adalimumab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug, in this Treatment Cycle. Patients may re-trial adalimumab after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

#### Note

Any queries concerning the arrangements to prescribe adalimumab may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are measured.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the indices of disease severity submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment authority is submitted within a treatment cycle and Medicare Australia will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

Patients who wish to trial a second or subsequent treatment cycle following a break in PBS-subsidised therapy of at least 5 years, must re-qualify for initial treatment with respect to both the indices of disease severity. Patients must have received treatment with methotrexate and sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured.

**Note**

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

Applications for treatment with adalimumab where the dosing frequency exceeds 40 mg per fortnight will not be approved.

Applications for treatment with adalimumab where they have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; and

(iii) patients wish to re-commence treatment with a specific biological agent following a break in PBS-subsidised therapy with that specific agent (Initial 2).

All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of therapy for all agents except for infliximab, for which a maximum of 22 weeks will be authorised. It is recommended that patients be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological agent supply.

Patients must be assessed for response to any course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

Grandfather patients — golimumab only.

Applications for patients who commenced treatment with golimumab prior to 1 March 2010 may apply for initial PBS-subsidised treatment as continuing therapy under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with any biological agent prior to PBS listing of that agent.

Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment for all agents. Approval will be based on the criteria included in the relevant restriction.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological agent, patients may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. Patients are eligible to receive continuing biological treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

Patients must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

(3) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate biological agent without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements.

Patients may swap to an alternate biological agent at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological agent at the time of the application or not.

Patients may alternate between therapy with any biological agent of their choice (1 at a time) providing:

(i) they have not received PBS-subsidised treatment with that particular biological agent previously; or

(ii) they have demonstrated an adequate response to that particular biological agent if they have previously trialled it on the PBS; or

(iii) they have not previously failed to respond to treatment 3 times in this Treatment Cycle.

To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the biological agent the patient is ceasing.

(4) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the indices of disease severity submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment authority is submitted within a treatment cycle and Medicare Australia will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

Patients who wish to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must re-qualify for initial treatment with respect to both the indices of disease severity. Patients must have received treatment with methotrexate and sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured.

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<th>No. of Premium</th>
<th>Dispensed</th>
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<td>36.90 Humira VE</td>
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<td>5</td>
<td>..</td>
<td>1774.70</td>
<td>36.90 Humira VE</td>
</tr>
</tbody>
</table>
ADALIMUMAB
Authority required
Active ankylosing spondylitis
Treatment Phase: Initial 1 (new patients)

Clinical criteria:

The condition must be radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis,

AND

Patient must not have received any PBS-subsidised treatment with either adalimumab, certolizumab pegol, etanercept, golimumab or infliximab in this treatment cycle,

AND

Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; or (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); or (iii) limitation of chest expansion relative to normal values for age and gender,

AND

Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months.

Population criteria:

Patient must be an adult.

Treatment criteria:

Must be treated by a rheumatologist.

The application must include details of the NSAIDs trialled, their doses and duration of treatment.

If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used.

If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication.

If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance.

The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application:

(a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; AND

(b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L.

The BASDAI must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. The BASDAI must be no more than 1 month old at the time of initial application.

Both ESR and CRP measures should be provided with the initial treatment application and both must be no more than 1 month old. If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form which must include the following:

(i) a copy of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and

(ii) a completed BASDAI Assessment Form; and

(iii) a completed Exercise Program Self Certification Form included in the supporting information form; and

(iv) a signed patient acknowledgment.

The assessment of the patient’s response to the initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted no later than 4 weeks from the cessation of that treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

A maximum of 16 weeks of treatment with this drug will be approved under this criterion.

Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) was approved in this cycle and the date of the first application under a new cycle.

Note

Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Department of Human Services website at www.humanservices.gov.au

Note
For details on the appropriate minimum exercise program that will be accepted for the purposes of administering this restriction, please refer to the Department of Human Services website at www.humanservices.gov.au

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

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

**Authority required**
Ankylosing spondylitis

Treatment Phase: Initial 2 (change or recommencement for all patients)

**Clinical criteria:**
Patient must have a documented history of active ankylosing spondylitis,

AND
Patient must have received prior PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition in this treatment cycle,

AND
Patient must not have failed PBS-subsidised therapy with this drug for this condition in the current treatment cycle,

AND
Patient must be eligible to receive further bDMARD therapy.

**Population criteria:**
Patient must be an adult.

**Treatment criteria:**
Must be treated by a rheumatologist.

Where the most recent course of PBS-subsidised bDMARD treatment was approved under either of the initial treatment restrictions (i.e. for patients with no prior PBS-subsidised bDMARD therapy or, under this restriction, for patients who have received previous PBS-subsidised bDMARD therapy) the patient must have been assessed for response to that course following a minimum of 12 weeks of treatment. These assessments must be provided to the Department of Human Services no later than 4 weeks from the date the course was ceased. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, patients must have been assessed for response, and the assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

The authority application must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form.

A maximum of 16 weeks of treatment with this drug will be approved under this criterion.

Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised bDMARD was approved in this cycle and the date of the first application under a new cycle.

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

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

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

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

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

**Note**
TREATMENT OF ADULT PATIENTS WITH ACTIVE ANKYLOSING SPONDYLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, certolizumab pegol,
A patient is eligible for PBS-subsidised treatment with only 1 of the 5 bDMARDs at any 1 time.

From 1 March 2007, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised bDMARDs without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a bDMARD while they continue to show a response to therapy.

A patient who received PBS-subsidised bDMARD treatment prior to 1 March 2007 is considered to be in their first cycle as of 1 March 2007. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once. A patient who, prior to 1 March 2007, was authorised to receive PBS-subsidised initial treatment for ankylosing spondylitis with the same agent twice, is exempt from this condition in respect of applications approved prior to 1 March 2007.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised bDMARD therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised bDMARD treatment in the most recent cycle to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or

(iii) a patient wishes to re-commence treatment with a specific bDMARD following a break in PBS-subsidised therapy with that agent (Initial 2).

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI), or the prior NSAID therapy and exercise program requirements.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements.

For a new patient, the BASDAI used to determine the baseline must be measured while the patient is receiving NSAID therapy and completing their exercise program.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with at least 1 NSAID, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the BASDAI, ESR and/or CRP levels are measured.

**Authority required**

Ankylosing spondylitis

Treatment Phase: Initial treatment – Initial 1 (new patients) or Initial 2 (change or recommencement for all patients) – balance of supply

**Clinical criteria:**

Patient must have active, or a documented history of active, ankylosing spondylitis,

AND

Patient must have received insufficient therapy with this drug under the Initial 1 (new patients) restriction to complete 16 weeks treatment; OR

Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement for all patients) restriction to complete 16 weeks treatment,

AND

The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Population criteria:**

Patient must be an adult.

**Treatment criteria:**

Must be treated by a rheumatologist.

**Note**

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

**Note**

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

**Note**

Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

**ADALIMUMAB**

**Authority required**

Ankylosing spondylitis

Treatment Phase: Continuing treatment

**Clinical criteria:**

Patient must have a documented history of active ankylosing spondylitis,

AND

Patient must have received this drug as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment in this treatment cycle,

AND

Patient must have demonstrated an adequate response to treatment with this drug.

**Population criteria:**

Patient must be an adult.

**Treatment criteria:**
Must be treated by a rheumatologist.

An adequate response is defined as an improvement from baseline of at least 2 of the BASDAI and 1 of the following:

(a) an ESR measurement no greater than 25 mm per hour; or
(b) a CRP measurement no greater than 10 mg per L; or
(c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and supplied in all subsequent continuing treatment applications.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and
(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form.

All measurements provided must be no more than 1 month old at the time of application.

A maximum of 24 weeks of treatment with this drug will be authorised under this criterion.

All applications for continuing treatment with this drug must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment following an initial treatment course it must be made following a minimum of 12 weeks of treatment with this drug. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised bDMARD was approved in this cycle and the date of the first application under a new cycle.

Note

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

Note

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

Note

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

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

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GPO Box 9826
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Note

TREATMENT OF ADULT PATIENTS WITH ACTIVE ANKYLOSING SPONDYLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, certolizumab pegol, etanercept, golimumab and infliximab for adult patients with active ankylosing spondylitis.

Where the term 'bDMARD' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 5 bDMARDs at any 1 time.

From 1 March 2007, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised bDMARDs without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a bDMARD while they continue to show a response to therapy.

A patient who received PBS-subsidised bDMARD treatment prior to 1 March 2007 is considered to be in their first cycle as of 1 March 2007.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once. A patient who, prior to 1 March 2007, was authorised to receive PBS-subsidised initial treatment for ankylosing spondylitis with the same agent twice, is exempt from this condition in respect of applications approved prior to 1 March 2007.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised bDMARD therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised bDMARD treatment in the most recent cycle to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
(ii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or
(iii) a patient wishes to re-commence treatment with a specific bDMARD following a break in PBS-subsidised therapy with that agent (Initial 2).

A patient must be assessed for response to every course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI), or the prior NSAID therapy and exercise program requirements.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements.

For a new patient, the BASDAI used to determine the baseline must be measured while the patient is receiving NSAID therapy and completing their exercise program.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with at least 1 NSAID, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the BASDAI, ESR and/or CRP levels are measured.

Authority required

Ankylosing spondylitis

Treatment Phase: Continuing treatment – balance of supply

Clinical criteria:

Patient must have a documented history of active ankylosing spondylitis,

AND

Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment,

AND

The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

Population criteria:
Patient must be an adult.

Treatment criteria:

Must be treated by a rheumatologist.

Note

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

Note

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

Note

Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

9104E

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges

1

5

.. 1774.70

36.90

Humira

9078T

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes

1

5

.. 1774.70

36.90

Humira

ADALIMUMAB

Authority required

Initial 1 (new patients)

Initial treatment of Crohn disease in a patient assessed by CDAI.

Initial PBS-subsidised treatment with adalimumab by a gastroenterologist or a consultant physician as specified in the NOTE below, of a patient with severe refractory Crohn disease who satisfies the following criteria:

(a) has confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician as specified in the NOTE below; and

(b) has signed a patient acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and

(c) has failed to achieve an adequate response to prior systemic therapy including:

(i) a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period; and

(ii) immunosuppressive therapy including:

— azathioprine at a dose of at least 2 mg per kg daily for 3 or more months; or

— 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months; or

— methotrexate at a dose of at least 15 mg weekly for 3 or more months.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of the accepted toxicities including severity can be found on the Medicare Australia website (www.medicareaustralia.gov.au).

The following initiation criterion indicates failure to achieve an adequate response and must be demonstrated in all patients at the time of the application:

(a) have a severity of disease activity which results in a Crohn Disease Activity Index (CDAI) Score greater than or equal to 300 as assessed.

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

The most recent CDAI assessment must be no more than 1 month old at the time of application.

Applications for authorisation must be made in writing and must include:

(a) two completed authority prescription forms; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) the completed current Crohn Disease Activity Index (CDAI) calculation sheet including the date of assessment of the patient’s condition; and
A maximum of 16 weeks treatment will be authorised under this criterion.

Two completed authority prescriptions must be submitted with every initial application for adalimumab. One prescription must be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats. The second prescription must be written for 2 doses of 40 mg and 2 repeats. Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with adalimumab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

A CDAI assessment of the patient’s response to this initial course of treatment must be made following a minimum of 12 weeks therapy so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with adalimumab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised adalimumab treatment

**Authority required**

**Initial 2**

Change or re-commencement of treatment of Crohn disease in a patient assessed by CDAI.

Initial PBS-subsidised treatment with adalimumab by a gastroenterologist or a consultant physician as specified in the NOTE below of a patient who:

(a) has a documented history of severe refractory Crohn disease; and

(b) in this treatment cycle, has received prior PBS-subsidised treatment with infliximab or adalimumab for this condition; and

(c) has not failed PBS-subsidised therapy with adalimumab for this condition more than once in the current treatment cycle.

**NOTE:** Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of TNF-alfa antagonist therapy within the timeframes specified in the relevant restriction.

Where the most recent course of PBS-subsidised TNF-alfa antagonist treatment was approved under an initial treatment restriction, the patient must have been assessed for response to that course following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

If the response assessment to the previous course of TNF-alfa antagonist treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of TNF-alfa antagonist.

**Authority applications must be made in writing and must include:**

(a) two completed authority prescription forms; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) the completed current Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient’s condition; and

(ii) details of prior TNF alfa antagonist treatment including details of date and duration of treatment.

Two completed authority prescriptions must be submitted with every initial application for adalimumab. One prescription must be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats. The second prescription must be written for 2 doses of 40 mg and 2 repeats. Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with adalimumab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

A CDAI assessment of the patient’s response to this initial course of treatment must be made following a minimum of 12 weeks therapy so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with adalimumab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised adalimumab treatment

**Authority required**

**Initial 1**

Initial treatment of Crohn disease in a patient with short gut syndrome or an ostomy patient.

Initial PBS-subsidised treatment with adalimumab by a gastroenterologist, or consultant physician as specified in the NOTE below of a patient who satisfies the following criteria:
(a) has confirmed Crohn disease defined by standard clinical, endoscopic and/or imaging features, including histological evidence with the diagnosis confirmed by a gastroenterologist or consultant physician as specified in the NOTE below; and

(b) has diagnostic imaging or surgical evidence of short gut syndrome or has an ileostomy or colostomy; and

(c) has evidence of intestinal inflammation; and

(d) has signed a patient acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and

(e) has failed to achieve an adequate response to prior systemic drug therapy including:

(i) a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period; and

(ii) immunosuppressive therapy including:

— azathioprine at a dose of at least 2 mg per kg daily for 3 or more months; or

— 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months; or

— methotrexate at a dose of at least 15 mg weekly for 3 or more months.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of the accepted toxicities including severity can be found on the Medicare Australia website (www.medicareaustralia.gov.au).

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the application:

(a) have evidence of intestinal inflammation, including:

(i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; AND/OR

(ii) faeces: higher than normal lactoferrin or calprotectin level; AND/OR

(iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery;

AND/OR

(b) be assessed clinically as being in a high faecal output state;

AND/OR

(c) be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of adalimumab.

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the continuing treatment restriction. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.

Applications for authorisation must be made in writing and must include:

(a) two completed authority prescription forms; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and

(ii) reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; and

(iii) date of the most recent clinical assessment; and

(iv) the signed patient acknowledgement.

All assessments, pathology tests and diagnostic imaging studies must be made within 1 month of the date of application.

A maximum of 16 weeks treatment will be authorised under this criterion.

Two completed authority prescriptions must be submitted with every initial application for adalimumab. One prescription must be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats. The second prescription must be written for 2 doses of 40 mg and 2 repeats. Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with adalimumab may be requested by telephone by contacting Medicare Australia on 1800 700 270 [hours of operation 8 a.m. to 5 p.m. EST Monday to Friday]. Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

The assessment of the patient’s response to this initial course of treatment must be made following a minimum of 12 weeks therapy so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare...
It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised adalimumab treatment

**Authority required**

**Initial 2**

Change or re-commencement of treatment of Crohn disease in a patient with short gut syndrome, an ostomy patient or a patient with extensive small intestine disease.

Initial PBS-subsidised treatment with adalimumab by a gastroenterologist or a consultant physician as specified in the NOTE below of a patient who:

- (a) has a documented history of severe refractory Crohn disease; and
- (b) in this treatment cycle, has received prior PBS-subsidised treatment with infliximab or adalimumab for this condition; and
- (c) has not failed PBS-subsidised therapy with adalimumab for this condition more than once in the current treatment cycle.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of TNF-alfa antagonist therapy within the timeframes specified in the relevant restriction.

Where the most recent course of PBS-subsidised TNF-alfa antagonist treatment was approved under an initial treatment restriction, the patient must have been assessed for response to that course following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

If the response assessment to the previous course of TNF-alfa antagonist treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of TNF-alfa antagonist.

Authority applications must be made in writing and must include:

- (a) two completed authority prescription forms; and
- (b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
  - (i) reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criteria, if relevant; and
  - (ii) details of prior TNF alfa antagonist treatment including details of date and duration of treatment.

A maximum of 16 weeks of treatment will be approved under this criterion.

Two completed authority prescriptions must be submitted with every initial application for adalimumab. One prescription must be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats. The second prescription must be written for 2 doses of 40 mg and 2 repeats. Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with adalimumab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

The assessment of the patient’s response to this initial course of treatment must be made following a minimum of 12 weeks of therapy so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with adalimumab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised adalimumab treatment

**Authority required**

**Initial 1**

Initial treatment of Crohn disease in a patient with extensive small intestine disease.

Initial PBS-subsidised treatment with adalimumab by a gastroenterologist or a consultant physician as specified in the NOTE below, of a patient with severe refractory Crohn disease who satisfies the following criteria:

- (a) has confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or consultant physician as specified in the NOTE below; and
- (b) has extensive small intestinal disease with radiological evidence of intestinal inflammation affecting more than 50 cm of the small intestine; and
- (c) has signed a patient acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and
- (d) has failed to achieve an adequate response to prior systemic therapy including:
  - (i) a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period; and
  - (ii) immunosuppressive therapy including:
    - azathioprine at a dose of at least 2 mg per kg daily for 3 or more months; or
    - 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months; or

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NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of the accepted toxicities including severity can be found on the Medicare Australia website (www.medicareaustralia.gov.au).

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the application:

(a) have severity of disease activity which results in a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220;
AND/OR
(b) have evidence of active intestinal inflammation, including:
(i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; AND/OR
(ii) faeces: higher than normal lactoferrin or calprotectin level; AND/OR
(iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery;
AND/OR
(c) be assessed clinically as being in a high faecal output state;
AND/OR
(d) be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of adalimumab.

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the continuing treatment restriction. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.

Applications for authorisation must be made in writing and must include:

(a) two completed authority prescription forms; and
(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and
(ii) (1) reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; or
(2) the completed current Crohn Disease Activity Index (CDAI) calculation sheet including the dates of assessment of the patient’s condition, if relevant; and
(iii) date of the most recent clinical assessment; and
(iv) the signed patient acknowledgement.

All assessments, pathology tests and diagnostic imaging studies must be made within 1 month of the date of application.

A maximum of 16 weeks treatment of adalimumab will be authorised under this criterion.

Two completed authority prescriptions must be submitted with every initial application for adalimumab. One prescription must be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats. The second prescription must be written for 2 doses of 40 mg and 2 repeats. Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with adalimumab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

The assessment of the patient’s response to this initial course of treatment must be made following a minimum of 12 weeks of therapy after the first dose so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with adalimumab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised adalimumab treatment

**Note**

Any queries concerning the arrangements to prescribe adalimumab may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.
TREATMENT OF ADULT PATIENTS WITH SEVERE REFRACTORY CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab and infliximab for adult patients with severe refractory Crohn disease. Where the term ‘tumour necrosis factor (TNF) alfa antagonist’ appears in the following NOTES and restrictions, it refers to adalimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 2 TNF-alfa antagonists at any 1 time.

From 1 August 2008, under the PBS, all patients will be able to commence a treatment cycle where they may trial each PBS-subsidised TNF-alfa antagonist without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a TNF-alfa antagonist while they continue to show a response to therapy.

A patient who received PBS-subsidised TNF-alfa antagonist treatment prior to 1 August 2008 is considered to be in their first cycle as of 1 August 2008. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised TNF-alfa antagonist more than twice.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised TNF-alfa antagonist therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised TNF-alfa antagonist treatment in the most recent cycle to the date of the first application for initial treatment with a TNF-alfa antagonist under the new treatment cycle.

A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised TNF-alfa antagonist therapy after 1 August 2008.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised TNF-alfa antagonist treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) TNF-alfa antagonist therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or

(iii) a patient wishes to re-commence treatment with a specific TNF-alfa antagonist following a break in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks of therapy for infliximab.

From 1 August 2008, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

For second and subsequent courses of PBS-subsidised TNF-alfa antagonist treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Adalimumab only: Two completed authority prescriptions must be submitted with every initial application for adalimumab. One prescription must be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats. The second prescription must be written for 2 doses of 40 mg and 2 repeats.

(b) Continuing treatment. Following the completion of an initial treatment course with a specific TNF-alfa antagonist, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing TNF-alfa antagonist treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted TNF-alfa antagonist supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that

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# ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

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**Note**

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**Packs**

**No. of Rpts**

**Premium $**

**Dispensed Price for Max. Qty $**

**Maximum Recordable Value for Safety Net $**

**Brand Name and Manufacturer**

335
courset was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised TNF-alfa antagonist is approved, a patient may swap if eligible to the alternate TNF-alfa antagonist within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Crohn Disease Activity Index (CDAI) Score, evidence of intestinal inflammation), or the prior corticosteroid therapy and immunosuppressive therapy.

A patient may trial the alternate TNF-alfa antagonist at any time, regardless of whether they are receiving therapy (initial or continuing) with a TNF-alfa antagonist at the time of the application. However, they cannot swap to a particular TNF-alfa antagonist if they have failed to respond to prior treatment with that drug two times within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to the alternate TNF-alfa antagonist should be accompanied by the approved authority prescription or remaining repeats for the TNF-alfa antagonist the patient is ceasing.

(3) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the CDAI or evidence of intestinal inflammation submitted with the first authority application for a TNF-alfa antagonist. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and Medicare Australia will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised TNF-alfa antagonist therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with a corticosteroid and at least 1 immunosuppressive agent, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the CDAI score or the indices of intestinal inflammation are measured.

(5) Patients ‘grandfathered’ onto PBS-subsidised treatment with adalimumab or infliximab.

A patient who commenced treatment with adalimumab for severe refractory Crohn disease prior to 9 November 2007 or infliximab prior to 7 March 2007 and who continues to receive treatment at the time of application, may qualify for treatment under the initial ‘grandfather’ treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with adalimumab or infliximab will be authorised under this criterion.

Following completion of the initial PBS-subsidised course, further applications for treatment with adalimumab or infliximab will be assessed under the continuing treatment restriction.

‘Grandfather’ arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a ‘grandfather’ patient must requalify for initial treatment under the criteria that apply to a new patient. See ‘Re-commencement of treatment after a 5-year break in PBS-subsidised therapy’ above for further details.

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

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ADALIMUMAB

Authority required

Initial 3 (grandfather)

Initial PBS-subsidised treatment of Crohn disease in a patient assessed by CDAI who has previously received non-PBS-subsidised therapy with adalimumab.

Initial PBS-subsidised supply for continuing treatment with adalimumab by a gastroenterologist, a consultant physician as specified in the NOTE below, or other consultant physician in consultation with a gastroenterologist of a patient who:

(a) has a documented history of severe refractory Crohn disease and was receiving treatment with adalimumab prior to 9 November 2007; and
(b) had a Crohn Disease Activity Index (CDAI) Score of greater than or equal to 300 prior to commencing treatment with adalimumab. Where a baseline CDAI assessment is not available, please call Medicare Australia on 1800 700 270 to discuss; and
(c) has signed a patient acknowledgement indicating that they understand and acknowledge that PBS-subsidised treatment will cease if they do not (2007/2008).
Patients may qualify for PBS-subsidised treatment under this restriction once only Monday to Friday.

Where fewer than 5 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

A maximum of 24 weeks treatment will be approved under this criterion.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to those patients who meet the continuation criterion.

Where fewer than 5 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Patients are eligible to receive continuing adalimumab treatment in courses of up to 24 weeks providing they continue to sustain the response. Patients are eligible to receive continuing adalimumab treatment in courses of up to 24 weeks providing they continue to sustain the response.

Where fewer than 5 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday)

**Authority required**

Continuing treatment of Crohn disease in a patient assessed by CDAI.

Continuing treatment of Crohn disease in a patient assessed by CDAI.

If the application is the first application for continuing treatment with adalimumab, a CDAI assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of therapy so that there is adequate time for a response to be demonstrated.

The assessment of the patient’s response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with adalimumab.

A maximum of 24 weeks treatment will be approved under this criterion.

Where fewer than 5 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Patients are eligible to receive continuing adalimumab treatment in courses of up to 24 weeks providing they continue to sustain the response. Patients are eligible to receive continuing adalimumab treatment in courses of up to 24 weeks providing they continue to sustain the response.

Where fewer than 5 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday)

**Authority required**

Continuing treatment of Crohn disease in a patient with short gut syndrome or an ostomy patient.

Continuing treatment of Crohn disease in a patient with short gut syndrome or an ostomy patient.
consultant physician in consultation with a gastroenterologist, of a patient who:

(a) has a documented history of severe refractory Crohn disease with intestinal inflammation and with short gut syndrome or with an ileostomy or colostomy; and

(b) has demonstrated or sustained an adequate response to treatment with adalimumab.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

An adequate response to adalimumab treatment is defined as:

(a) improvement of intestinal inflammation as demonstrated by:

(i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; AND/OR

(ii) faeces: normalisation of lactoferrin or calprotectin level; AND/OR

(iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or

(b) reversal of high faecal output state; or

(c) avoidance of the need for surgery or total parenteral nutrition (TPN).

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) the reports and dates of the pathology or diagnostic imaging test(s) used to assess response to therapy or the date of clinical assessment.

The patient’s assessment must be no more than 1 month old at the time of application.

If the application is the first application for continuing treatment with adalimumab, an assessment of the patient’s response to this initial course of treatment must be made following a minimum of 12 weeks of therapy after the first dose so that there is adequate time for a response to be demonstrated.

The assessment of the patient’s response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with adalimumab.

Patients are eligible to receive continuing adalimumab treatment in courses of up to 24 weeks providing they continue to sustain the response.

A maximum of 24 weeks of treatment will be authorised under this criterion.

Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday)

Authority required

Continuing treatment of Crohn disease in a patient with extensive small intestine disease.

Continuing PBS-subsidised treatment with adalimumab by a gastroenterologist, or consultant physician as specified in the NOTE below or other consultant physician in consultation with a gastroenterologist, of a patient who:

(a) has a documented history of severe refractory Crohn disease with extensive intestinal inflammation affecting more than 50 cm of the small intestine; and

(b) has demonstrated or sustained an adequate response to treatment with adalimumab.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

An adequate response to adalimumab treatment is defined as:

(a) a reduction in Crohn Disease Activity Index (CDAI) Score to no greater than 150; or

(b) improvement of intestinal inflammation as demonstrated by:

(i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; AND/OR

(ii) faeces: normalisation of lactoferrin or calprotectin level; AND/OR

(iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or

(c) reversal of high faecal output state; or

(d) avoidance of the need for surgery or total parenteral nutrition (TPN).

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
The patient's assessment must be no more than 1 month old at the time of application. The baseline CDAI assessments must be from immediately prior to commencing treatment with adalimumab. Where a baseline assessment is not available, please call Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) to discuss.

The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with adalimumab. Patients are eligible to receive continuing adalimumab treatment in courses of up to 24 weeks providing they continue to sustain the response. A maximum of 24 weeks treatment will be authorised under this criterion.

Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Authority required**

**Initial 3**

Initial PBS-subsidised supply for continuing treatment with adalimumab by a gastroenterologist, a consultant physician as specified in the NOTE below, or other consultant physician in consultation with a gastroenterologist, of a patient who:

(a) has a documented history of severe refractory Crohn disease and was receiving treatment with adalimumab prior to 9 November 2007; and

(b) (1) has a history of extensive small intestinal disease with radiological evidence of intestinal inflammation affecting more than 50 cm of the small intestine; or

(2) has diagnostic imaging or surgical evidence of short gut syndrome or has an ileostomy or colostomy with a documented history of intestinal inflammation; and

(c) has signed a patient acknowledgement indicating that they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and

(d) has demonstrated or sustained an adequate response to treatment with adalimumab according to the criteria included in the relevant continuation restriction. For advice please contact Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**NOTE:** Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

The same criteria used to determine an inadequate response to prior treatment at baseline must be used to determine response to treatment and eligibility for continuing therapy, according to the criteria included in the continuing treatment restriction.

An adequate response to adalimumab treatment is defined as:

(a) a reduction in Crohn Disease Activity Index (CDAI) Score to no greater than 150; or

(b) improvement of intestinal inflammation as demonstrated by:

(i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; AND/OR

(ii) faeces: normalisation of lactoferrin or calprotectin level; AND/OR

(iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or

(c) reversal of high faecal output state; or

(d) avoidance of the need for surgery or total parenteral nutrition (TPN).

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) (1) the completed current and baseline Crohn Disease Activity Index (CDAI) Score calculation sheet, where relevant, including the date of the assessment of the patient's condition; or

(2) the reports and dates of the current and baseline pathology or diagnostic imaging test(s) in order to assess response to therapy; or

(3) the date of clinical assessment(s); and

(ii) the signed patient acknowledgement.

The patient's assessment must be no more than 1 month old at the time of application. The baseline CDAI assessments must be from immediately prior to commencing treatment with adalimumab. Where a baseline assessment is not available, please call Medicare Australia on 1800 700 270 to discuss.
Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised TNF-alfa antagonist therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised TNF-alfa antagonist treatment in the most recent cycle to the date of the assessment of the patient’s response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with adalimumab.

Patients are eligible to receive continuing adalimumab treatment in courses of up to 24 weeks providing they continue to sustain the response. Patients who fail to demonstrate or sustain a response to treatment with adalimumab for Crohn disease as specified in the criteria for continuing treatment with adalimumab, will not be eligible to recommence PBS-subsidised treatment with this drug within 12 months of the date on which treatment was ceased.

A maximum of 24 weeks treatment will be authorised under this criterion.

Where fewer than 5 repeats are requested at the time of this application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Patients may qualify for PBS-subsidised treatment under this restriction once only

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

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe adalimumab should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Note
TREATMENT OF ADULT PATIENTS WITH SEVERE REFRACTORY CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab and infliximab for adult patients with severe refractory Crohn disease. Where the term ‘tumour necrosis factor (TNF) alfa antagonist’ appears in the following NOTES and restrictions, it refers to adalimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 2 TNF-alfa antagonists at any 1 time.

From 1 August 2008, under the PBS, all patients will be able to commence a treatment cycle where they may trial each PBS-subsidised TNF-alfa antagonist without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a TNF-alfa antagonist while they continue to show a response to therapy.

A patient who received PBS-subsidised TNF-alfa antagonist treatment prior to 1 August 2008 is considered to be in their first cycle as of 1 August 2008.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised TNF-alfa antagonist more than twice.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised TNF-alfa antagonist therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised TNF-alfa antagonist treatment in the most recent cycle to the date of the first application for initial treatment with a TNF-alfa antagonist under the new treatment cycle.

A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised TNF-alfa antagonist therapy after 1 August 2008.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised TNF-alfa antagonist treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) TNF-alfa antagonist therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or

(iii) a patient wishes to re-commence treatment with a specific TNF-alfa antagonist following a break in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks of therapy for
ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

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From 1 August 2008, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

For second and subsequent courses of PBS-subsidised TNF-alfa antagonist treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Adalimumab only: Two completed authority prescriptions must be submitted with every initial application for adalimumab. One prescription must be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats. The second prescription must be written for 2 doses of 40 mg and 2 repeats.

(b) Continuing treatment. Following the completion of an initial treatment course with a specific TNF-alfa antagonist, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing TNF-alfa antagonist treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted TNF-alfa antagonist supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised TNF-alfa antagonist is approved, a patient may swap if eligible to the alternate TNF-alfa antagonist within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Crohn Disease Activity Index (CDAI) Score, evidence of intestinal inflammation), or the prior corticosteroid therapy and immunosuppressive therapy.

A patient may trial the alternate TNF-alfa antagonist at any time, regardless of whether they are receiving therapy (initial or continuing) with a TNF-alfa antagonist at the time of the application. However, they cannot swap to a particular TNF-alfa antagonist if they have failed to respond to prior treatment with that drug two times within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to the alternate TNF-alfa antagonist should be accompanied by the approved authority prescription or remaining repeats for the TNF-alfa antagonist the patient is ceasing.

(3) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the CDAI or evidence of intestinal inflammation submitted with the first authority application for a TNF-alfa antagonist. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and Medicare Australia will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised TNF-alfa antagonist therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with a corticosteroid and at least 1 immunosuppressive agent, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the CDAI score or the indices of intestinal inflammation are measured.

(5) Patients ‘grandfathered’ onto PBS-subsidised treatment with adalimumab or infliximab.

A patient who commenced treatment with adalimumab for severe refractory Crohn disease prior to 9 November 2007 or infliximab prior to 7 March 2007 and who continues to receive treatment at the time of application, may qualify for treatment under the initial ‘grandfather’ treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with adalimumab or infliximab will be authorised under this criterion.

Following completion of the initial PBS-subsidised course, further applications for treatment with adalimumab or infliximab will be assessed under the continuing treatment restriction.

‘Grandfather’ arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a ‘grandfather’ patient must requalify for initial treatment under the criteria that apply to a new patient. See ‘Re-commencement of treatment after a 5-year break in PBS-subsidised therapy’ above for further details.

Note

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

Authority required

Initial treatment [Initial 1, Whole body (New patients — No prior biological agent)]

Initial treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over who:

(a) have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis; and

(b) have not received any prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle; and

(c) have signed a patient and prescriber acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment with adalimumab is not to be used as initial treatment for psoriasis.

A maximum of 16 weeks of treatment with adalimumab will be authorised under this restriction.

An application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed severe chronic plaque psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient’s condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; and

(iii) the signed patient and prescriber acknowledgements.

A maximum of 16 weeks of treatment with adalimumab will be authorised under this restriction.

Where fewer than 4 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period beyond 16 weeks.

A PASI assessment of the patient’s response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with adalimumab. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised adalimumab treatment.

Authority required

Initial or re-Treatment [Initial 2, Whole body (Received prior biological agent under PBS)]

Treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over who:

(a) have a documented history of severe chronic plaque psoriasis; and

(b) have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle; and

(c) have not failed PBS-subsidised therapy with adalimumab for the treatment of this condition in the current Treatment Cycle.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity to necessitate permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of acceptable toxicities including severity, associated with phototherapy, methotrexate, cyclosporin and acitretin, can be found on the Medicare Australia website (www.medicareaustralia.gov.au).

The following initiation criterion indicates failure to achieve an adequate response and must be demonstrated in all patients at the time of the application:

(a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 1 month old at the time of application.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient’s condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; and

(iii) the signed patient and prescriber acknowledgements.

A maximum of 16 weeks of treatment with adalimumab will be authorised under this restriction.

Where fewer than 4 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period beyond 16 weeks.

A PASI assessment of the patient’s response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with adalimumab. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised adalimumab treatment.

Authority required

Initial or re-Treatment [Initial 2, Whole body (Received prior biological agent under PBS)]

Treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over who:

(a) have a documented history of severe chronic plaque psoriasis; and

(b) have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle; and

(c) have not failed PBS-subsidised therapy with adalimumab for the treatment of this condition in the current Treatment Cycle.
Applications for authorisation must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient’s condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and
(ii) details of prior biological treatment, including dosage, date and duration of treatment.

Applications for patients who have demonstrated a response to PBS-subsidised adalimumab treatment within this Treatment Cycle and who wish to re-commence adalimumab treatment within the same Cycle following a break in therapy, will only be approved where evidence of the patient’s response to their most recent course of PBS-subsidised adalimumab treatment has been submitted to Medicare Australia within 1 month of cessation of treatment.

A maximum of 16 weeks of treatment with adalimumab will be authorised under this restriction.
Where fewer than 4 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial period beyond 16 weeks.

A PASI assessment of the patient’s response to this course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with adalimumab. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised adalimumab treatment.

A PASI assessment of the patient’s response to their most recent course of PBS-subsidised adalimumab treatment has been submitted to Medicare Australia within 1 month of cessation of treatment.

Patients who fail to demonstrate a response to PBS-subsidised adalimumab treatment within this Treatment Cycle and who wish to re-commence adalimumab treatment within the same Cycle following a break in therapy, will only be approved where evidence of the patient’s response to their most recent course of PBS-subsidised adalimumab treatment has been submitted to Medicare Australia within 1 month of cessation of treatment.

A maximum of 16 weeks of treatment with adalimumab will be authorised under this restriction.
Where fewer than 4 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial period beyond 16 weeks.

A PASI assessment of the patient’s response to this course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with adalimumab. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised adalimumab treatment.

Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may re-commence adalimumab treatment within the same Cycle following a break in therapy, will only be approved where evidence of the patient’s response to their most recent course of PBS-subsidised adalimumab treatment has been submitted to Medicare Australia within 1 month of cessation of treatment.

A maximum of 16 weeks of treatment with adalimumab will be authorised under this restriction.
Where fewer than 4 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial period beyond 16 weeks.

A PASI assessment of the patient’s response to this course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with adalimumab. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised adalimumab treatment.

Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may re-commence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle

**Authority required**

Initial treatment [Initial 1, Face, hand, foot (New patients — No prior biological agent)]

Initial treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over who:
(a) have severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis; and
(b) have not received any prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle; and
(c) have signed a patient and prescriber acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment (face, hand, foot); and
(d) have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 3 of the following 4 treatments:
(i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or
(ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; and/or
(iii) cyclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; and/or
(iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity to necessitate permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of acceptable toxicities including severity, associated with phototherapy, methotrexate, cyclosporin and acitretin, can be found on the Medicare Australia website (www.medicareaustralia.gov.au).

The following initiation criterion indicates failure to achieve an adequate response and must be demonstrated in all patients at the time of the application:
(a) Chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:
(i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment; or
(ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.
(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.
(c) The most recent PASI assessment must be no more than 1 month old at the time of application.
Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient’s condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and

(ii) details of previous phototherapy and systemic drug therapy (dose where applicable), date of commencement and duration of therapy); and

(iii) the signed patient and prescriber acknowledgements.

A maximum of 16 weeks of treatment with adalimumab will be authorised under this restriction.

Where fewer than 4 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period beyond 16 weeks.

A PASI assessment of the patient’s response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with adalimumab. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised adalimumab treatment.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

**Authority required**

Initial or re-Treatment [Initial 2, Face, hand, foot (Received prior biological agent under PBS)]

Treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over who:

(a) have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot; and

(b) have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle; and

(c) have not failed PBS-subsidised therapy with adalimumab for the treatment of this condition in the current Treatment Cycle.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient’s condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and

(ii) details of prior biological treatment, including dosage, date and duration of treatment.

Applications for patients who have demonstrated a response to PBS-subsidised adalimumab treatment within this Treatment Cycle and who wish to re-commence adalimumab treatment within the same Cycle following a break in therapy, will only be approved where evidence of the patient’s response to their most recent course of PBS-subsidised adalimumab treatment has been submitted to Medicare Australia within 1 month of cessation of treatment.

A maximum of 16 weeks of treatment with adalimumab will be authorised under this restriction.

Where fewer than 4 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period beyond 16 weeks.

A PASI assessment of the patient’s response to this course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with adalimumab. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised adalimumab treatment.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may re-commence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

**Note**

Any queries concerning the arrangements to prescribe adalimumab may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period beyond 16 weeks.
There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the body part.

How to prescribe biological agents for the treatment of severe chronic plaque psoriasis after 1 March 2010.

There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime. Patients are eligible to continue to receive continuous treatment for chronic plaque psoriasis until they fail to meet the response criteria.

Therefore once a patient fails to meet the response criteria for a PBS-subsidised biological agent, they must change to an alternate agent if they wish to continue PBS-subsidised biological treatment. A patient who, prior to 1 March 2010, was authorised to receive PBS-subsidised initial treatment with a biological agent is exempt from this condition in respect of applications approved prior to 1 March 2010.

Patients must be assessed for response to each course of continuing treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a Treatment Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological agent therapy before they are eligible to commence the next Cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological agent treatment in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Treatment Cycle.

Patients for whom a break in PBS-subsidised therapy of less than 5 years duration has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle.

There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime. How to prescribe biological agents for the treatment of severe chronic plaque psoriasis after 1 March 2010.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Application for approval for initial treatment.

Applications for a course of initial treatment should be made in the following situations:

(i) patients who have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); or

(ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under ‘(4) Swapping therapy’ below]; or

(iii) patients who wish to re-commence treatment following a break in PBS-subsidised therapy with that agent (Initial 2).

All applications for initial treatment will be limited to provide for a maximum of 16 weeks of treatment in the case of adalimumab and etanercept, 22 weeks of treatment in the case of infliximab and 28 weeks of treatment in the case of ustekinumab.

(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological agent, a PASI assessment must be conducted after at least 12 weeks of treatment. This assessment must be submitted to Medicare Australia within 1 month of the completion of this initial treatment course. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

(3) Application for continuing treatment.

Following the completion of an initial treatment course of a biological agent to which an adequate response has been demonstrated, patients may qualify to receive up to 24 weeks of continuing treatment with that biological agent. Patients are eligible to continue to receive continuous...
treatment with 24 week courses providing they continue to sustain a response.

For second and subsequent courses of PBS-subsidised treatment with adalimumab, etanercept, infliximab or ustekinumab it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Where a response assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to sustain a response to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

(4) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate agent within the same Treatment Cycle without having to requalify with respect to disease severity (i.e. a PASI score of greater than 15), or prior treatment requirements.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

Patients may trial an alternate biological agent at any time, regardless of whether they are receiving therapy with a biological agent at the time of the application or not. However, they cannot swap to a particular agent if they have failed to respond to treatment with that particular agent within the same Cycle.

Patients who commenced treatment with adalimumab prior to 1 June 2009 or ustekinumab prior to 1 March 2010 access these interchangeability arrangements in the same way as patients who have not.

To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the agent being ceased.

(5) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment authority is submitted within a Treatment Cycle and subsequent response will be assessed according to this revised PASI score.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

(6) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

Patients who wish to trial a second or subsequent Biological Treatment Cycle, following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment according to the criteria of the relevant restriction and index of disease severity. Patients must have had at least 1 prior treatment, as listed in the criteria, for a minimum of 6 weeks, and must have a PASI assessment conducted preferably whilst still on treatment, but no later than 1 month following cessation of treatment. The PASI assessment must be no older than 1 month at the time of application.

Note

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

Note

Special Pricing Arrangements apply.

9426D  adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges

9425C  adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes

**adalimumab**

**Authority required**

Continuing treatment (Whole body)

Continuing PBS-subsidised treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over:

(a) who have a documented history of severe chronic plaque psoriasis; and

(b) whose most recent course of PBS-subsidised biological treatment for this condition in this Treatment Cycle was with adalimumab; and

(c) who have demonstrated an adequate response to their most recent course of treatment with adalimumab.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the pre-biological treatment baseline value for this Treatment Cycle.

This assessment must be provided to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with adalimumab, the assessment of response must be after a minimum of 12 weeks of treatment with an initial course.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare
A maximum of 24 weeks of treatment with adalimumab will be authorised under this restriction.

Approval will be based on the PASI assessment of response to the most recent course of treatment with adalimumab.

A maximum of 24 weeks of treatment with adalimumab will be authorised under this restriction. Where fewer than 5 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for continuing authority applications, or for treatment that would otherwise extend the treatment period beyond 24 weeks.

A PASI assessment of the patient’s response must be conducted within 4 weeks prior to completion of this course of treatment. This assessment, which will be used to determine eligibility for further continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with adalimumab. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised adalimumab treatment.

Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may re-commence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

**Authority required**

Continuing treatment (Face, hand, foot)

Continuing PBS-subsidised treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over:

(a) who have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot; and

(b) whose most recent course of PBS-subsidised biological treatment for this condition in this Treatment Cycle was with adalimumab; and

(c) who have demonstrated an adequate response to treatment with adalimumab.

An adequate response to adalimumab treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the pre-biological treatment baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the pre-biological treatment baseline value.

This assessment must be provided to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with adalimumab, the assessment of response must be after a minimum of 12 weeks of treatment with an initial course.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams along with the date of the assessment of the patient’s condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

The most recent PASI assessment must be no more than 1 month old at the time of application.

A maximum of 24 weeks of treatment with adalimumab will be authorised under this restriction. Where fewer than 5 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for continuing authority applications, or for treatment that would otherwise extend the treatment period beyond 24 weeks.

A PASI assessment of the patient’s response must be conducted within 4 weeks prior to completion of this course of treatment. This assessment, which will be used to determine eligibility for further continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with adalimumab. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised adalimumab treatment.

Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may re-commence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

**Note**
Any queries concerning the arrangements to prescribe adalimumab may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authority to prescribe adalimumab should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Note
TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, etanercept, infliximab and ustekinumab, for adult patients with severe chronic plaque psoriasis. Therefore, where the term ‘biological agents’ appears in the following NOTES and restrictions, it only refers to adalimumab, etanercept, infliximab and ustekinumab.

From 1 March 2010, all patients will be able to commence a ‘Biological Treatment Cycle’ (Cycle), where they may trial adalimumab, etanercept, infliximab or ustekinumab without having to meet the initial treatment criteria, that is they will not need to experience a disease flare when swapping to an alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

A patient who received PBS-subsidised biological agent treatment for chronic plaque psoriasis prior to 1 March 2010 is considered to be in their first Cycle as of 1 March 2010.

Patients are eligible for PBS-subsidised treatment with only 1 biological agent at any 1 time.

Within the same Treatment Cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for a PBS-subsidised biological agent, they must change to an alternate agent if they wish to continue PBS-subsidised biological treatment. A patient who, prior to 1 March 2010, was authorised to receive PBS-subsidised initial treatment for chronic plaque psoriasis with the same agent twice, is exempt from this condition in respect of applications approved prior to 1 March 2010.

Patients must be assessed for response to each course of continuing treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a Treatment Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological agent therapy before they are eligible to commence the next Cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological agent treatment in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Treatment Cycle.

Patients for whom a break in PBS-subsidised therapy of less than 5 years duration has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle.

There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe chronic plaque psoriasis after 1 March 2010.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Application for approval for initial treatment.

Applications for a course of initial treatment should be made in the following situations:

(i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); or

(ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under ‘(4) Swapping therapy’ below]; or

(iii) patients who wish to re-commence treatment following a break in PBS-subsidised therapy with that agent (Initial 2).

All applications for initial treatment will be limited to provide for a maximum of 16 weeks of treatment in the case of adalimumab and etanercept, 22 weeks of treatment in the case of infliximab and 28 weeks of treatment in the case of ustekinumab.

(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological agent, a PASI assessment must be conducted after at least 12 weeks of treatment. This assessment must be submitted to Medicare Australia within 1 month of the completion of this initial treatment course. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

(3) Application for continuing treatment.

Following the completion of an initial treatment course of a biological agent to which an adequate response has been demonstrated, patients may qualify to receive up to 24 weeks of continuing treatment with that biological agent. Patients are eligible to continue to receive continuous...
treatment with 24 week courses providing they continue to sustain a response.

For second and subsequent courses of PBS-subsidised treatment with adalimumab, etanercept, infliximab or ustekinumab it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Where a response assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to sustain a response to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

(4) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate agent within the same Treatment Cycle without having to requalify with respect to disease severity (i.e. a PASI score of greater than 15), or prior treatment requirements.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

Patients may trial an alternate biological agent at any time, regardless of whether they are receiving therapy with a biological agent at the time of the application or not. However, they cannot swap to a particular agent if they have failed to respond to treatment with that particular agent within the same Cycle.

Patients who commenced treatment with adalimumab prior to 1 June 2009 or ustekinumab prior to 1 March 2010 access these interchangeability arrangements in the same way as patients who have not.

To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the agent being ceased.

(5) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment authority is submitted within a Treatment Cycle and subsequent response will be assessed according to this revised PASI score.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatment applications.

(6) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

Patients who wish to trial a second or subsequent Biological Treatment Cycle, following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment according to the criteria of the relevant restriction and index of disease severity. Patients must have had at least 1 prior treatment, as listed in the criteria, for a minimum of 6 weeks, and must have a PASI assessment conducted preferably whilst still on treatment, but no later than 1 month following cessation of treatment. The PASI assessment must be no older than 1 month at the time of application.

Note

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

Note

Special Pricing Arrangements apply.

9428F
adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges
1 5 .. 1774.70 36.90 Humira VE

9427E
adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes
1 5 .. 1774.70 36.90 Humira VE

CERTOLIZUMAB PEGOL

Authority required

Active ankylosing spondylitis

Treatment Phase: Initial 1 (new patients)

Clinical criteria:

The condition must be radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis,

AND

Patient must not have received any PBS-subsidised treatment with either adalimumab, certolizumab pegol, etanercept, golimumab or infliximab in this treatment cycle,

AND

Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; or (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); or (iii) limitation of chest expansion relative to normal values for age and gender,

AND

Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst
<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>Dispensed Price for Max. Qty $</th>
<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
</table>

**Antineoplastic and Immunomodulating Agents**

**Population criteria:**

Patient must be an adult.

**Treatment criteria:**

Must be treated by a rheumatologist.

The application must include details of the NSAIDs trialled, their doses and duration of treatment.

If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used.

If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication.

If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance.

The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application:

(a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; AND

(b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L.

The BASDAI must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. The BASDAI must be no more than 1 month old at the time of initial application.

Both ESR and CRP measures should be provided with the initial treatment application and both must be no more than 1 month old. If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form which must include the following:

(i) a copy of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and

(ii) a completed BASDAI Assessment Form; and

(iii) a completed Exercise Program Self Certification Form included in the supporting information form; and

(iv) a signed patient acknowledgment.

The assessment of the patient’s response to the initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted no later than 4 weeks from the cessation of that treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

A maximum of 18 to 20 weeks of treatment with this drug will be approved under this criterion.

Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) was approved in this cycle and the date of the first application under a new cycle.

**Note**

Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Department of Human Services website at www.humanservices.gov.au

**Note**

For details on the appropriate minimum exercise program that will be accepted for the purposes of administering this restriction, please refer to the Department of Human Services website at www.humanservices.gov.au

**Note**

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

**Note**

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

**Authority required**

Ankylosing spondylitis

**Treatment Phase:** Initial 2 (change or recommencement for all patients)

**Clinical criteria:**

Patient must have a documented history of active ankylosing spondylitis,

AND

Patient must have received prior PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition in this treatment cycle,

AND

Patient must not have failed PBS-subsidised therapy with this drug for this condition in the current treatment cycle,
Patient must be eligible to receive further bDMARD therapy.

**Population criteria:**
Patient must be an adult.

**Treatment criteria:**
Must be treated by a rheumatologist.

Where the most recent course of PBS-subsidised bDMARD treatment was approved under either of the initial treatment restrictions (i.e. for patients with no prior PBS-subsidised bDMARD therapy or, under this restriction, for patients who have received previous PBS-subsidised bDMARD therapy) the patient must have been assessed for response to that course following a minimum of 12 weeks of treatment. These assessments must be provided to the Department of Human Services no later than 4 weeks from the date the course was ceased. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, patients must have been assessed for response, and the assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

The authority application must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form.

A maximum of 18 to 20 weeks of treatment with this drug will be approved under this criterion.

Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised bDMARD was approved in this cycle and the date of the first application under a new cycle.

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

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

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

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

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

**Note**
TREATMENT OF ADULT PATIENTS WITH ACTIVE ANKYLOSING SPONDYLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, certolizumab pegol, etanercept, golimumab and infliximab for adult patients with active ankylosing spondylitis.

Where the term 'bDMARD' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 5 bDMARDs at any 1 time.

From 1 March 2007, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised bDMARDs without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a bDMARD while they continue to show a response to therapy.

A patient who received PBS-subsidised bDMARD treatment prior to 1 March 2007 is considered to be in their first cycle as of 1 March 2007.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once. A patient who, prior to 1 March 2007, was authorised to receive PBS-subsidised initial treatment for ankylosing spondylitis with the same agent twice, is exempt from this condition in respect of applications approved prior to 1 March 2007.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised bDMARD therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised bDMARD treatment in the most recent cycle to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.
To ensure a patient receives the same treatment cycle, it must be ensured that the patient remains eligible to receive continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
(ii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or
(iii) a patient wishes to re-commence treatment with a specific bDMARD following a break in PBS-subsidised therapy with that agent (Initial 2).

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

For second and subsequent courses of PBS-subsidised bDMARD treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI), or the prior NSAID therapy and exercise program requirements.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements.

For a new patient, the BASDAI used to determine the baseline must be measured while the patient is receiving NSAID therapy and completing their exercise program.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with at least 1 NSAID, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the BASDAI, ESR and/or CRP levels are measured.

**Authority required**

Ankylosing spondylitis

Treatment Phase: Initial treatment – Initial 1 (new patients) or Initial 2 (change or recommencement for all patients) – balance of supply

**Clinical criteria:**

Patient must have active, or a documented history of active, ankylosing spondylitis,

AND

Patient must have received insufficient therapy with this drug under the Initial 1 (new patients) restriction to complete 18 to 20 weeks treatment; OR

Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement for all patients) restriction to complete 18 to 20 weeks treatment,

AND
The treatment must provide no more than the balance of up to 18 to 20 weeks treatment available under the above restrictions.

Population criteria:
Patient must be an adult.

Treatment criteria:
Must be treated by a rheumatologist.

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

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

Note
Authority approval for sufficient therapy to complete a maximum of 18 to 20 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 18 to 20 weeks of treatment should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Authority required
Ankylosing spondylitis
Treatment Phase: Continuing treatment

Clinical criteria:
Patient must have a documented history of active ankylosing spondylitis,
AND
Patient must have received this drug as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment in this treatment cycle,
AND
Patient must have demonstrated an adequate response to treatment with this drug.

Population criteria:
Patient must be an adult.

Treatment criteria:
Must be treated by a rheumatologist.

An adequate response is defined as an improvement from baseline of at least 2 of the BASDAI and 1 of the following:
(a) an ESR measurement no greater than 25 mm per hour; or
(b) a CRP measurement no greater than 10 mg per L; or
(c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and supplied in all subsequent continuing treatment applications.

The authority application must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form.

All measurements provided must be no more than 1 month old at the time of application.

A maximum of 24 weeks of treatment with this drug will be authorised under this criterion.

All applications for continuing treatment with this drug must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment following an initial treatment course it must be made following a minimum of 12 weeks of treatment with this drug. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised bDMARD was approved in this cycle and the date of the first application under a new cycle.

Note
No increase in the maximum quantity or number of units may be authorised.
From 1 March 2007, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised treatment with only 1 of the 5 bDMARDs at any 1 time.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD within the same treatment cycle, providing they continue to show a response to therapy. Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a bDMARD while they continue to show a response to therapy.

Where the term ‘bDMARD’ appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab and infliximab only.

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, certolizumab pegol, etanercept, golimumab and infliximab for adult patients with active ankylosing spondylitis.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new course of treatment within the same treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) (further details are under ‘Swapping therapy’ below); or

(iii) a patient wishes to re-commence treatment with a specific bDMARD following a break in PBS-subsidised therapy with that agent (Initial 2).

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:
cycle without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI), or the prior NSAID therapy and exercise program requirements.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements.

For a new patient, the BASDAI used to determine the baseline must be measured while the patient is receiving NSAID therapy and completing their exercise program.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with at least 1 NSAID, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the BASDAI, ESR and/or CRP levels are measured.

**Authority required**

Ankylosing spondylitis

**Treatment Phase:** Continuing treatment – balance of supply

**Clinical criteria:**

Patient must have a documented history of active ankylosing spondylitis,

AND

Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment,

AND

The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Population criteria:**

Patient must be an adult.

**Treatment criteria:**

Must be treated by a rheumatologist.

**Note**

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

**Note**

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

**Note**

Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

10137M
certolizumab pegol 200 mg/mL injection, 2 x 1 mL syringes 1 5 .. 1708.98 36.90 Cimzia

**CERTOLIZUMAB PEGOL**

**Authority required**

Initial 1 (new patient or patient re-commencing after a break of more than 24 months)

Initial PBS-subsidised treatment with certolizumab pegol, by a rheumatologist or clinical immunologist with expertise in the management of
rheumatoid arthritis, of adults who:

(a) have severe active rheumatoid arthritis; and

(b) have received no PBS-subsidised treatment with a bDMARD for this condition in the previous 24 months; and

(c) have failed, in the 24 months immediately prior to the date of application, to achieve an adequate response to at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs), which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be:

— hydroxychloroquine at a dose of at least 200 mg daily; or
— leflunomide at a dose of at least 10 mg daily; or
— sulfasalazine at a dose of at least 2 g daily.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, then the 6 months of intensive DMARD treatment must include at least 3 months continuous treatment with each of at least 2 of the DMARDs:

— hydroxychloroquine at a dose of at least 200 mg daily; and/or
— leflunomide at a dose of at least 10 mg daily; and/or
— sulfasalazine at a dose of at least 2 g daily.

The application must include details of the contraindication or intolerance to methotrexate. Details of the toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose can be found on the Medicare Australia website [www.medicareaustralia.gov.au]. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

If 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved product information or cannot be tolerated at the doses specified above, then one or more of the following DMARDs may be used in place of these agents in order to satisfy the requirement for a trial of 6 months of intensive DMARD therapy with at least 2 DMARDs taken continuously for at least 3 months each:

— azathioprine at a dose of at least 1 mg/kg per day; and/or
— cyclosporin at a dose of at least 2 mg/kg/day; and/or
— sodium aurothiomalate at a dose of 50 mg weekly.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances. Details of the toxicities, including severity, which will be accepted as a reason for substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial can be found on the Medicare Australia website [www.medicareaustralia.gov.au].

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance and dose for each DMARD must be provided in the authority application. Details of the toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy can be found on the Medicare Australia website [www.medicareaustralia.gov.au].

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

(i) a total active joint count of at least 20 active (swollen and tender) joints; or
(ii) at least 4 active joints from the following list of major joints:

— elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
— shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website [www.medicareaustralia.gov.au]]; and
Patients who fail to respond to treatment with certolizumab pegol under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**Authority required**

Initial course of PBS-subsidised treatment with certolizumab pegol, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults who:

1. have a documented history of severe active rheumatoid arthritis; and
2. have received prior PBS-subsidised bDMARD treatment for this condition and are eligible to receive further bDMARD therapy.

The authority application must be made in writing and must include:

1. a completed authority prescription form; and
2. a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

Applications for patents who have received PBS-subsidised treatment with certolizumab pegol and who wish to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised certolizumab pegol treatment, within the timeframes specified below.

A maximum of 18 to 20 weeks of treatment depending on the dosage regimen will be authorised under this restriction.

Where fewer than 5 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 18 or 20 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Where the most recent course of PBS-subsidised certolizumab pegol treatment was approved under either of the initial 1 or 2 treatment restrictions, patients must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be provided to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised certolizumab pegol treatment was approved under the continuing treatment criteria, patients must have been assessed for response, and the assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Patients who fail to demonstrate a response to treatment with certolizumab pegol under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**Authority required**

Continuing treatment with certolizumab pegol, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults who:

1. have a documented history of severe active rheumatoid arthritis; and
2. have demonstrated an adequate response to treatment with certolizumab pegol; and
3. whose most recent course of PBS-subsidised bDMARD treatment was with certolizumab pegol.

An adequate response to treatment is defined as:

- an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;
- either of the following:
  1. a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
  2. a reduction in the number of the following major active joints, from at least 4, by at least 50%:
     - elbow, wrist and/or ankle (assessed as swollen and tender); and/or
     - shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The authority application must be made in writing and must include:

1. a completed authority prescription form; and
2. a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].
A maximum of 24 weeks of treatment will be approved under this restriction.

Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

All applications for continuing treatment with certolizumab pegol must include a measurement of response to the prior course of therapy. This assessment must be provided to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with certolizumab pegol, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

Patients who fail to demonstrate a response to treatment with certolizumab pegol under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**Note**

Any queries concerning the arrangements to prescribe certolizumab pegol may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Further prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe certolizumab pegol should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

**Note**

**TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying anti-rheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) α antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab) and the T-cell co-stimulation modulator (abatacept).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

PBS-subsidised abatacept, golimumab, infliximab and rituximab must be used in combination with methotrexate at a dose of at least 7.5 mg weekly. Where a patient cannot tolerate 7.5 mg of methotrexate weekly, they are eligible to receive PBS-subsidised adalimumab, certolizumab pegol, etanercept and tocilizumab.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-α antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:

— a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,

— a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and

— once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-α antagonist prior to 1 August 2010 please contact Medicare Australia on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised therapy is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or

(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or

(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or

(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).
Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment. Abatacept patients:

- Prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient’s weight with no repeats applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab.
- Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that rituximab.

Rituximab patients:

- Must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to Medicare Australia within 4 weeks.
- Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:

- Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients, two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient’s weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:

- A further application may be submitted to Medicare Australia 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Rituximab patients:

- A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.
- Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate [ESR], the C-reactive protein [CRP] levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However, the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept patients:

- Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.
TREATMENT OF PATIENTS UNDER 18 YEARS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing of etanercept under the Pharmaceutical Benefits Scheme (PBS) for patients under 18 years with severe chronic plaque psoriasis.

Applications for treatment of this condition will be limited to provide patients with a maximum of 24 weeks of therapy per course of treatment. A maximum of 16 weeks treatment with etanercept will be authorised for the primary application. The balance, a further 8 weeks treatment, will be authorised if the submitted Psoriasis Area and Severity Index (PASI) assessment demonstrates an adequate response to treatment. Where fewer than 3 repeats are requested at the time of the authority application, authorizations for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Applications for a course of initial treatment should be made for patients who have received no prior PBS-subsidised biological treatment and wish to commence such therapy.

(1) Application for approval for initial treatment.

Applications for a course of initial treatment should be made for patients who have received no prior PBS-subsidised biological treatment and wish to commence such therapy.

(2) Applications for approval for re-treatment.

Applications for re-treatment with etanercept should be made in the following situations:

(i) a patient who has received prior PBS-subsidised etanercept and experiences a disease flare, and wishes to start a second or subsequent treatment course with etanercept following a break of less than 12 months in PBS-subsidised therapy; or

(ii) a patient who has received and failed to respond to prior PBS-subsidised etanercept and wishes to start a second or subsequent treatment course following a break of less than 12 months in PBS-subsidised therapy.

For psoriasis affecting the whole body:

Patients are eligible for re-treatment due to disease flare if there is a 50% or greater change in the patients PASI score or the patient has a current PASI score of greater than 15, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.

For psoriasis affecting the face, hands, or feet:

Patients are eligible for re-treatment due to disease flare if:

(i) all subscores are rated moderate to severe or 2 of the three subscores are rated severe to very severe; OR

(ii) the skin area affected is a 50% or greater change or the area affected is 30% or more of the face, palm of a hand or sole of a foot, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.

(3) Applications for approval for completion of a course

Applications for a further 8 weeks of treatment to allow for completion of 24 weeks of therapy should be submitted with a PASI assessment.

The PASI assessment must be conducted after at least 12 weeks of treatment.

This assessment must be submitted to Department of Human Services (the Department) within 1 month of the completion of 12 weeks of treatment. Where a response assessment is not undertaken and submitted to the Department within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department on 1800 700 270 to discuss.
ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

(4) Baseline measurements to determine response.

The Department will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for etanercept. However, prescribers may provide new baseline measurements any time that an initial or re-treatment authority is submitted and subsequent response will be assessed according to this revised PASI score.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of gaining approval for the remainder of 24 weeks treatment.

(5) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment course with etanercept following a break in PBS-subsidised etanercept therapy of at least 12 months, must requalify for treatment under the initial treatment restriction. The most recent PASI assessment must be no more than 1 month old at the time of application.

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment (whole body)

Clinical criteria:

The treatment must be as systemic monotherapy; OR

The treatment must be in combination with methotrexate,

AND

Patient must have lesions present for at least 6 months from the time of initial diagnosis,

AND

Patient must not have received any prior PBS-subsidised treatment with etanercept for this condition; OR

Patient must not have received any PBS-subsidised treatment with etanercept for this condition for at least 12 months,

AND

Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 3 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or (ii) methotrexate at a dose of at least 10 mg or 10 mg per square metre weekly (whichever is lowest) for at least 6 weeks; and/or (iii) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks,

AND

Patient must not receive more than 16 weeks of treatment with etanercept under this restriction.

Population criteria:

Patient must be under 18 years of age and a parent or authorised guardian must have signed a patient acknowledgement.

Treatment criteria:

Must be treated by a dermatologist.

Where treatment with any of the above-mentioned drugs was contraindicated according to the relevant TGA-approved Product Information, or where phototherapy was contraindicated, details must be provided at the time of application.

Where intolerance to phototherapy, methotrexate and/or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in a patient at the time of the application:

(a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 1 month old at the time of application.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis in Patients Less Than 18 Years PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient’s condition and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; and

(iii) the parent or authorised guardian signed patient and prescriber acknowledgements.

Where a patient has had a 12 month treatment break, the length of the break is measured from the date the most recent treatment was stopped to the date of the application to re-commence treatment.

Note

Details of acceptable toxicities including severity, associated with phototherapy, methotrexate and acitretin, can be found on the Department of Human Services website at www.humanservices.gov.au
Note
Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

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

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

Note
Special Pricing Arrangements apply.

Authority required
TREATMENT OF PATIENTS UNDER 18 YEARS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing of etanercept under the Pharmaceutical Benefits Scheme (PBS) for patients under 18 years with severe chronic plaque psoriasis.

Applications for treatment of this condition will be limited to provide patients with a maximum of 24 weeks of therapy per course of treatment. A maximum of 16 weeks treatment with etanercept will be authorised for the primary application. The balance, a further 8 weeks treatment, will be authorised if the submitted Psoriasis Area and Severity Index (PASI) assessment demonstrates an adequate response to treatment. Where fewer than 3 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone.

Once a patient has failed to respond to treatment 2 times, they must have, at a minimum, a 12 month break. The length of a treatment break is measured from the date the most recent treatment was stopped to the date of the first application for initial treatment.

There are separate restrictions for treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Application for approval for initial treatment.

Applications for a course of initial treatment should be made for patients who have received no prior PBS-subsidised biological treatment and wish to commence such therapy.

(2) Applications for approval for re-treatment.

Applications for re-treatment with etanercept should be made in the following situations:

(i) a patient who has received prior PBS-subsidised etanercept and experiences a disease flare, and wishes to start a second or subsequent treatment course with etanercept following a break of less than 12 months in PBS-subsidised therapy; or

(ii) a patient who has received and failed to respond to prior PBS-subsidised etanercept and wishes to start a second or subsequent treatment course following a break of less than 12 months in PBS-subsidised therapy.

For psoriasis affecting the whole body:

Patients are eligible for re-treatment due to disease flare if there is a 50% or greater change in the patient's PASI score or the patient has a current PASI score of greater than 15, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.

For psoriasis affecting the face, hand or foot:

Patients are eligible for re-treatment due to disease flare if:

(i) all subscores are rated moderate to severe or 2 of the three subscores are rated severe to very severe; OR

(ii) the skin area affected is a 50% or greater change or the area affected is 30% or more of the face, palm of a hand or sole of a foot, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.

(3) Applications for approval for completion of a course

Applications for a further 8 weeks of treatment to allow for completion of 24 weeks of therapy should be submitted with a PASI assessment.

The PASI assessment must be conducted after at least 12 weeks of treatment.

This assessment must be submitted to Department of Human Services (the Department) within 1 month of the completion of 12 weeks of treatment. Where a response assessment is not undertaken and submitted to the Department within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department on 1800 700 270 to discuss.

(4) Baseline measurements to determine response.

The Department will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with
To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of gaining approval for the remainder of 24 weeks treatment.

(5) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment course with etanercept following a break in PBS-subsidised etanercept therapy of at least 12 months, must requalify for treatment under the initial treatment restriction. The most recent PASI assessment must be no more than 1 month old at the time of application.

Severe chronic plaque psoriasis

Clinical criteria:

The treatment must be as systemic monotherapy; OR

The treatment must be in combination with methotrexate,

AND

Patient must have received insufficient therapy under the Initial treatment (whole body) restriction for severe chronic plaque psoriasis to complete 16 weeks treatment; OR

Patient must have received insufficient therapy under the Re-treatment (whole body) restriction for severe chronic plaque psoriasis to complete 16 weeks treatment,

AND

The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Treatment criteria:

Must be treated by a dermatologist.

Note

Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:

Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Note

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

Note

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

Note

Special Pricing Arrangements apply.

Authority required

TREATMENT OF PATIENTS UNDER 18 YEARS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing of etanercept under the Pharmaceutical Benefits Scheme (PBS) for patients under 18 years with severe chronic plaque psoriasis.

Applications for treatment of this condition will be limited to provide patients with a maximum of 24 weeks of therapy per course of treatment. A maximum of 16 weeks treatment with etanercept will be authorised for the primary application. The balance, a further 8 weeks treatment, will be authorised if the submitted Psoriasis Area and Severity Index (PASI) assessment demonstrates an adequate response to treatment. Where fewer than 3 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone.

Once a patient has failed to respond to treatment 2 times, they must have, at a minimum, a 12 month break. The length of a treatment break is measured from the date the most recent treatment was stopped to the date of the first application for initial treatment.

There are separate restrictions for treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Application for approval for initial treatment.

Applications for a course of initial treatment should be made for patients who have received no prior PBS-subsidised biological treatment and wish to commence such therapy.

(2) Applications for approval for re-treatment.

Applications for re-treatment with etanercept should be made in the following situations:

(i) a patient who has received prior PBS-subsidised etanercept and experiences a disease flare, and wishes to start a second or subsequent
treatment course with etanercept following a break of less than 12 months in PBS-subsidised therapy; or

(ii) a patient who has received and failed to respond to prior PBS-subsidised etanercept and wishes to start a second or subsequent treatment course following a break of less than 12 months in PBS-subsidised therapy.

For psoriasis affecting the whole body:

Patients are eligible for re-treatment due to disease flare if there is a 50% or greater change in the patients PASI score or the patient has a current PASI score of greater than 15, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.

For psoriasis affecting the face, hand or foot:

Patients are eligible for re-treatment due to disease flare if:

(i) all subscores are rated moderate to severe or 2 of the three subscores are rated severe to very severe; OR

(ii) the skin area affected is a 50% or greater change or the area affected is 30% or more of the face, palm of a hand or sole of a foot, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.

(3) Applications for approval for completion of a course

Applications for a further 8 weeks of treatment to allow for completion of 24 weeks of therapy should be submitted with a PASI assessment. The PASI assessment must be conducted after at least 12 weeks of treatment.

This assessment must be submitted to Department of Human Services (the Department) within 1 month of the completion of 12 weeks of treatment. Where a response assessment is not undertaken and submitted to the Department within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department on 1800 700 270 to discuss.

(4) Baseline measurements to determine response.

The Department will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for etanercept. However, prescribers may provide new baseline measurements any time that an initial or re-treatment authority is submitted and subsequent response will be assessed according to this revised PASI score.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of gaining approval for the remainder of 24 weeks treatment.

(5) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment course with etanercept following a break in PBS-subsidised etanercept therapy of at least 12 months, must requalify for treatment under the initial treatment restriction. The most recent PASI assessment must be no more than 1 month old at the time of application.

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment or Re-treatment (Whole body) - completion of course

Clinical criteria:

The treatment must be as systemic monotherapy; OR

The treatment must be in combination with methotrexate,

AND

Patient must have received 16 weeks treatment under the Initial treatment (whole body) restriction for severe chronic plaque psoriasis; OR

Patient must have received 16 weeks treatment under the Re-treatment (whole body) restriction for severe chronic plaque psoriasis,

AND

Patient must have demonstrated an adequate response to treatment,

AND

Patient must not receive more than 8 weeks of treatment with etanercept under this restriction.

Treatment criteria:

Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, when compared with the pre-etanercept treatment baseline value.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) the completed current Psoriasis Area and Severity Index (PASI) calculation sheet including the date of assessment of the patient’s condition.

The same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of gaining approval for the remainder of 24 weeks treatment.

A PASI assessment of the patient’s response to the initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for a further 8 weeks of treatment, must be submitted no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with etanercept.
ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
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**Note**

It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their initial 16 week treatment course to ensure continuity of treatment for those patients who meet the eligibility criterion for a further 8 weeks of PBS-subsidised etanercept treatment.

**Note**

In circumstances where it is not possible to submit a response assessment after 12 weeks of treatment, please call the Department of Human Services on 1800 700 270 to discuss.

**Note**

The Department of Human Services will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for etanercept.

**Note**

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

**Note**

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

**Note**

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

**Note**

Special Pricing Arrangements apply.

**Authority required**

TREATMENT OF PATIENTS UNDER 18 YEARS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing of etanercept under the Pharmaceutical Benefits Scheme (PBS) for patients under 18 years with severe chronic plaque psoriasis.

Applications for treatment of this condition will be limited to provide patients with a maximum of 24 weeks of therapy per course of treatment. A maximum of 16 weeks treatment with etanercept will be authorised for the primary application. The balance, a further 8 weeks treatment, will be authorised if the submitted Psoriasis Area and Severity Index (PASI) assessment demonstrates an adequate response to treatment. Where fewer than 3 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone.

Once a patient has failed to respond to treatment 2 times, they must have, at a minimum, a 12 month break. The length of a treatment break is measured from the date the most recent treatment was stopped to the date of the first application for initial treatment.

There are separate restrictions for treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Application for approval for initial treatment.

Applications for a course of initial treatment should be made for patients who have received no prior PBS-subsidised biological treatment and wish to commence such therapy.

(2) Applications for approval for re-treatment.

Applications for re-treatment with etanercept should be made in the following situations:

(i) a patient who has received prior PBS-subsidised etanercept and experiences a disease flare, and wishes to start a second or subsequent treatment course with etanercept following a break of less than 12 months in PBS-subsidised therapy; or

(ii) a patient who has received and failed to respond to prior PBS-subsidised etanercept and wishes to start a second or subsequent treatment course following a break of less than 12 months in PBS-subsidised therapy.

For psoriasis affecting the whole body:

Patients are eligible for re-treatment due to disease flare if there is a 50% or greater change in the patients PASI score or the patient has a current PASI score of greater than 15, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.

For psoriasis affecting the face, hand or foot:

Patients are eligible for re-treatment due to disease flare if:

(i) all subscores are rated moderate to severe or 2 of the three subscores are rated severe to very severe; OR

(ii) the skin area affected is a 50% or greater change or the area affected is 30% or more of the face, palm of a hand or sole of a foot, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.
Applications for a further 8 weeks of treatment to allow for completion of 24 weeks of therapy should be submitted with a PASI assessment. The PASI assessment must be conducted after at least 12 weeks of treatment. This assessment must be submitted to Department of Human Services (the Department) within 1 month of the completion of 12 weeks of treatment. Where a response assessment is not undertaken and submitted to the Department within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department on 1800 700 270 to discuss.

(4) Baseline measurements to determine response.

The Department will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for etanercept. However, prescribers may provide new baseline measurements any time that an initial or re-treatment authority is submitted and subsequent response will be assessed according to this revised PASI score.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of gaining approval for the remainder of 24 weeks treatment.

(5) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment course with etanercept following a break in PBS-subsidised etanercept therapy of at least 12 months, must requalify for treatment under the initial treatment restriction. The most recent PASI assessment must be no more than 1 month old at the time of application.

Severe chronic plaque psoriasis

Treatment Phase: Re-treatment (Whole body)

Clinical criteria:

The treatment must be as systemic monotherapy; OR

The treatment must be in combination with methotrexate,

AND

Patient must have a documented history of severe chronic plaque psoriasis of the whole body,

AND

Patient must have received prior PBS-subsidised treatment with etanercept for this condition in the past 12 months,

AND

Patient must have demonstrated a response to etanercept and experienced a disease flare; OR

Patient must not have failed more than once to achieve an adequate response with etanercept,

AND

Patient must not receive more than 16 weeks of treatment with etanercept under this restriction.

Population criteria:

Patient must be under 18 years of age.

Treatment criteria:

Must be treated by a dermatologist.

A patient is eligible for re-treatment due to disease flare if there is a 50% or greater change in the patients PASI score or the patient has a current PASI score of greater than 15, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis in Patients Less Than 18 Years PBS Authority Application - Supporting Information which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient’s condition; and

(ii) details of prior etanercept treatment, including date ceased.

Where a patient has had a treatment break the length of the break is measured from the date the most recent treatment was stopped to the date of the application for further treatment.

Note

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

Note

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Note

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

Note

Special Pricing Arrangements apply.

Authority required

TREATMENT OF PATIENTS UNDER 18 YEARS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing of etanercept under the Pharmaceutical Benefits Scheme (PBS) for patients under 18 years with severe chronic plaque psoriasis.

Applications for treatment of this condition will be limited to provide patients with a maximum of 24 weeks of therapy per course of treatment. A maximum of 16 weeks treatment with etanercept will be authorised for the primary application. The balance, a further 8 weeks treatment, will be authorised if the submitted Psoriasis Area and Severity Index (PASI) assessment demonstrates an adequate response to treatment. Where fewer than 3 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone.

Once a patient has failed to respond to treatment 2 times, they must have, at a minimum, a 12 month break. The length of a treatment break is measured from the date the most recent treatment was stopped to the date of the first application for initial treatment.

There are separate restrictions for treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Application for approval for initial treatment.

Applications for a course of initial treatment should be made for patients who have received no prior PBS-subsidised biological treatment and wish to commence such therapy.

(2) Applications for approval for re-treatment.

Applications for re-treatment with etanercept should be made in the following situations:

(i) a patient who has received prior PBS-subsidised etanercept and experiences a disease flare, and wishes to start a second or subsequent treatment course with etanercept following a break of less than 12 months in PBS-subsidised therapy; or

(ii) a patient who has received and failed to respond to prior PBS-subsidised etanercept and wishes to start a second or subsequent treatment course following a break of less than 12 months in PBS-subsidised therapy.

For psoriasis affecting the whole body:

Patients are eligible for re-treatment due to disease flare if there is a 50% or greater change in the patients PASI score or the patient has a current PASI score of greater than 15, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.

For psoriasis affecting the face, hand or foot:

Patients are eligible for re-treatment due to disease flare if:

(i) all subscores are rated moderate to severe or 2 of the three subscores are rated severe to very severe; OR

(ii) the skin area affected is a 50% or greater change or the area affected is 30% or more of the face, palm of a hand or sole of a foot, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.

(3) Applications for approval for completion of a course

Applications for a further 8 weeks of treatment to allow for completion of 24 weeks of therapy should be submitted with a PASI assessment. The PASI assessment must be conducted after at least 12 weeks of treatment.

This assessment must be submitted to Department of Human Services (the Department) within 1 month of the completion of 12 weeks of treatment. Where a response assessment is not undertaken and submitted to the Department within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department on 1800 700 270 to discuss.

(4) Baseline measurements to determine response.

The Department will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for etanercept. However, prescribers may provide new baseline measurements any time that an initial or re-treatment authority is submitted and subsequent response will be assessed according to this revised PASI score.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of gaining approval for the remainder of 24 weeks treatment.

(5) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment course with etanercept following a break in PBS-subsidised etanercept therapy of at least 12 months, must requalify for treatment under the initial treatment restriction. The most recent PASI assessment must be no more than 1...
month old at the time of application.

Severe chronic plaque psoriasis

Treatmen phase: initial treatment (face, hand, foot)

Clinical criteria:

The treatment must be as systemic monotherapy; OR

The treatment must be in combination with methotrexate,

AND

Patient must have the plaque or plaques of the face, or palm of hand or sole of foot present for at least 6 months from the time of initial diagnosis,

AND

Patient must not have received any prior PBS-subsidised treatment with etanercept for this condition; OR

Patient must not have received any PBS-subsidised treatment with etanercept for this condition for at least 12 months,

AND

Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 3 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or (ii) methotrexate at a dose of at least 10 mg or 10 mg per square metre weekly (whichever is lowest) for at least 6 weeks; and/or (iii) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks,

AND

Patient must not receive more than 16 weeks of treatment with etanercept under this restriction.

Population criteria:

Patient must be under 18 years of age and a parent or authorised guardian must have signed a patient acknowledgement.

Treatment criteria:

Must be treated by a dermatologist.

Where treatment with any of the above-mentioned drugs was contraindicated according to the relevant TGA-approved Product Information, or where phototherapy was contraindicated, details must be provided at the time of application.

Where intolerance to phototherapy, methotrexate and/or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in a patient at the time of the application:

(a) Chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:

(i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment; or

(ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment;

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 1 month old at the time of application.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis in Patients Less Than 18 Years PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets, and face, hand, foot area diagrams including the dates of assessment of the patient’s condition

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; and

(iii) the parent or authorised guardian signed patient and prescriber acknowledgements.

Where a patient has had a 12 month treatment break, the length of the break is measured from the date the most recent treatment was stopped to the date of the application to re commence treatment.

Note

Details of acceptable toxicities including severity, associated with phototherapy, methotrexate and acitretin, can be found on the Department of Human Services website at www.humanservices.gov.au

Note

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

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

Applications for authority to prescribe should be forwarded to:
TREATMENT OF PATIENTS UNDER 18 YEARS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing of etanercept under the Pharmaceutical Benefits Scheme (PBS) for patients under 18 years with severe chronic plaque psoriasis.

Applications for treatment of this condition will be limited to provide patients with a maximum of 24 weeks of therapy per course of treatment. A maximum of 16 weeks treatment with etanercept will be authorised for the primary application. The balance, a further 8 weeks treatment, will be authorised if the submitted Psoriasis Area and Severity Index (PASI) assessment demonstrates an adequate response to treatment. Where fewer than 3 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone.

Once a patient has failed to respond to treatment 2 times, they must have, at a minimum, a 12 month break. The length of a treatment break is measured from the date the most recent treatment was stopped to the date of the first application for initial treatment.

There are separate restrictions for treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Application for approval for initial treatment.

Applications for a course of initial treatment should be made for patients who have received no prior PBS-subsidised biological treatment and wish to commence such therapy.

(2) Applications for approval for re-treatment.

Applications for re-treatment with etanercept should be made in the following situations:

(i) a patient who has received prior PBS-subsidised etanercept and experiences a disease flare, and wishes to start a second or subsequent treatment course with etanercept following a break of less than 12 months in PBS-subsidised therapy; or

(ii) a patient who has received and failed to respond to prior PBS-subsidised etanercept and wishes to start a second or subsequent treatment course following a break of less than 12 months in PBS-subsidised therapy.

For psoriasis affecting the whole body:

Patients are eligible for re-treatment due to disease flare if there is a 50% or greater change in the patient’s PASI score or the patient has a current PASI score of greater than 15, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.

For psoriasis affecting the face, hand or foot:

Patients are eligible for re-treatment due to disease flare if:

(i) all subscores are rated moderate to severe or 2 of the three subscores are rated severe to very severe; OR

(ii) the skin area affected is a 50% or greater change or the area affected is 30% or more of the face, palm of a hand or sole of a foot, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.

(3) Applications for approval for completion of a course

Applications for a further 8 weeks of treatment to allow for completion of 24 weeks of therapy should be submitted with a PASI assessment.

The PASI assessment must be conducted after at least 12 weeks of treatment.

This assessment must be submitted to Department of Human Services (the Department) within 1 month of the completion of 12 weeks of treatment. Where a response assessment is not undertaken and submitted to the Department within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department on 1800 700 270 to discuss.

(4) Baseline measurements to determine response.

The Department will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for etanercept. However, prescribers may provide new baseline measurements any time that an initial or re-treatment authority is submitted and subsequent response will be assessed according to this revised PASI score.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of gaining approval for the remainder of 24 weeks treatment.

(5) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment course with etanercept following a break in PBS-subsidised etanercept therapy of
Severe chronic plaque psoriasis

Treatment Phase: Initial treatment of Re-treatment (Face, hand, foot) - balance of first supply

Clinical criteria:
The treatment must be as systemic monotherapy; OR
The treatment must be in combination with methotrexate.

AND
Patient must have received insufficient therapy under the Initial treatment (Face, hand, foot) restriction for severe chronic plaque psoriasis to complete 16 weeks treatment; OR
Patient must have received insufficient therapy under the Re-treatment (Face, hand, foot) restriction for severe chronic plaque psoriasis to complete 16 weeks treatment,

AND
The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Treatment criteria:
Must be treated by a dermatologist.

Note
Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

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

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

Note
Special Pricing Arrangements apply.

Authority required
TREATMENT OF PATIENTS UNDER 18 YEARS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing of etanercept under the Pharmaceutical Benefits Scheme (PBS) for patients under 18 years with severe chronic plaque psoriasis.

Applications for treatment of this condition will be limited to provide patients with a maximum of 24 weeks of therapy per course of treatment. A maximum of 16 weeks treatment with etanercept will be authorised for the primary application. The balance, a further 8 weeks treatment, will be authorised if the submitted Psoriasis Area and Severity Index (PASI) assessment demonstrates an adequate response to treatment. Where fewer than 3 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone.

Once a patient has failed to respond to treatment 2 times, they must have, at a minimum, a 12 month break. The length of a treatment break is measured from the date the most recent treatment was stopped to the date of the first application for initial treatment.

There are separate restrictions for treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Application for approval for initial treatment.
Applications for a course of initial treatment should be made for patients who have received no prior PBS-subsidised biological treatment and wish to commence such therapy.

(2) Applications for approval for re-treatment.
Applications for re-treatment with etanercept should be made in the following situations:
(i) a patient who has received prior PBS-subsidised etanercept and experiences a disease flare, and wishes to start a second or subsequent treatment course with etanercept following a break of less than 12 months in PBS-subsidised therapy; or
(ii) a patient who has received and failed to respond to prior PBS-subsidised etanercept and wishes to start a second or subsequent treatment course following a break of less than 12 months in PBS-subsidised therapy.

For psoriasis affecting the whole body:
Patients are eligible for re-treatment due to disease flare if there is a 50% or greater change in the patients PASI score or the patient has a current PASI score of greater than 15, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised
etanercept.

For psoriasis affecting the face, hand or foot:

Patients are eligible for re-treatment due to disease flare if:

(i) all subscores are rated moderate to severe or 2 of the three subscores are rated severe to very severe; OR

(ii) the skin area affected is a 50% or greater change or the area affected is 30% or more of the face, palm of a hand or sole of a foot, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.

(3) Applications for approval for completion of a course

Applications for a further 8 weeks of treatment to allow for completion of 24 weeks of therapy should be submitted with a PASI assessment.

The PASI assessment must be conducted after at least 12 weeks of treatment. This assessment must be submitted to Department of Human Services (the Department) within 1 month of the completion of 12 weeks of treatment. Where a response assessment is not undertaken and submitted to the Department within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department on 1800 700 270 to discuss.

(4) Baseline measurements to determine response.

The Department will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for etanercept. However, prescribers may provide new baseline measurements any time that an initial or re-treatment authority is submitted and subsequent response will be assessed according to this revised PASI score.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of gaining approval for the remainder of 24 weeks treatment.

(5) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment course with etanercept following a break in PBS-subsidised etanercept therapy of at least 12 months, must requalify for treatment under the initial treatment restriction. The most recent PASI assessment must be no more than 1 month old at the time of application.

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment or Re-treatment (Face, hand, foot) - completion of course

Clinical criteria:

The treatment must be as systemic monotherapy; OR

The treatment must be in combination with methotrexate, AND

Patient must have received 16 weeks treatment under the Initial treatment (Face, hand, foot) restriction for severe chronic plaque psoriasis; OR

Patient must have received 16 weeks treatment under the Re-treatment (Face, hand, foot) restriction for severe chronic plaque psoriasis, AND

Patient must have demonstrated an adequate response to treatment, AND

Patient must not receive more than 8 weeks of treatment with etanercept under this restriction.

Treatment criteria:

Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the PASI symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the pre-biological treatment baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the pre-biological treatment baseline value.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) the completed current Psoriasis Area and Severity Index (PASI) calculation sheet including the date of assessment of the patient's condition.

The same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of gaining approval for the remainder of 24 weeks treatment.

A PASI assessment of the patient's response to the initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for a further 8 weeks of treatment, must be submitted no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with etanercept.

Note

It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their initial 16 week treatment course to ensure continuity of treatment for those patients who meet the eligibility criterion for a further 8 weeks of PBS-subsidised etanercept treatment.

Note
In circumstances where it is not possible to submit a response assessment after 12 weeks of treatment, please call the Department of Human Services on 1800 700 270 to discuss.

Note
The Department of Human Services will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for etanercept.

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

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Note
No increase in the maximum number of repeats may be authorised.

Note
Special Pricing Arrangements apply.

Authority required
TREATMENT OF PATIENTS UNDER 18 YEARS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing of etanercept under the Pharmaceutical Benefits Scheme (PBS) for patients under 18 years with severe chronic plaque psoriasis.

Applications for treatment of this condition will be limited to provide patients with a maximum of 24 weeks of therapy per course of treatment. A maximum of 16 weeks treatment with etanercept will be authorised for the primary application. The balance, a further 8 weeks treatment, will be authorised if the submitted Psoriasis Area and Severity Index (PASI) assessment demonstrates an adequate response to treatment. Where fewer than 3 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone.

Once a patient has failed to respond to treatment 2 times, they must have, at a minimum, a 12 month break. The length of a treatment break is measured from the date the most recent treatment was stopped to the date of the first application for initial treatment.

There are separate restrictions for treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Application for approval for initial treatment.
Applications for a course of initial treatment should be made for patients who have received no prior PBS-subsidised biological treatment and wish to commence such therapy.

(2) Applications for approval for re-treatment.
Applications for re-treatment with etanercept should be made in the following situations:
(i) a patient who has received prior PBS-subsidised etanercept and experiences a disease flare, and wishes to start a second or subsequent treatment course with etanercept following a break of less than 12 months in PBS-subsidised therapy; or
(ii) a patient who has received and failed to respond to prior PBS-subsidised etanercept and wishes to start a second or subsequent treatment course following a break of less than 12 months in PBS-subsidised therapy.

For psoriasis affecting the whole body:
Patients are eligible for re-treatment due to disease flare if there is a 50% or greater change in the patients PASI score or the patient has a current PASI score of greater than 15, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.

For psoriasis affecting the face, hand or foot:
Patients are eligible for re-treatment due to disease flare if:
(i) all subscores are rated moderate to severe or 2 of the three subscores are rated severe to very severe; or
(ii) the skin area affected is a 50% or greater change or the area affected is 30% or more of the face, palm of a hand or sole of a foot, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.

(3) Applications for approval for completion of a course
Applications for a further 8 weeks of treatment to allow for completion of 24 weeks of therapy should be submitted with a PASI assessment.
The PASI assessment must be conducted after at least 12 weeks of treatment.

This assessment must be submitted to Department of Human Services (the Department) within 1 month of the completion of 12 weeks of treatment.
ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

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</thead>
</table>

Where a response assessment is not undertaken and submitted to the Department within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department on 1800 700 270 to discuss.

(4) Baseline measurements to determine response.

The Department will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for etanercept. However, prescribers may provide new baseline measurements any time that an initial or re-treatment authority is submitted and subsequent response will be assessed according to this revised PASI score.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of gaining approval for the remainder of 24 weeks treatment.

(5) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment course with etanercept following a break in PBS-subsidised etanercept therapy of at least 12 months, must requalify for treatment under the initial treatment restriction. The most recent PASI assessment must be no more than 1 month old at the time of application.

Severe chronic plaque psoriasis

Treatment Phase: Re-treatment (Face, hand, foot)

**Clinical criteria:**

- The treatment must be as systemic monotherapy; OR
- The treatment must be in combination with methotrexate, AND
- Patient must have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot, AND
- Patient must have received prior PBS-subsidised treatment with etanercept for this condition in the past 12 months, AND
- Patient must have demonstrated a response to etanercept and experienced a disease flare; OR
- Patient must not have failed more than once to achieve an adequate response with etanercept, AND
- Patient must not receive more than 16 weeks of treatment with etanercept under this restriction.

**Population criteria:**

- Patient must be under 18 years of age.

**Treatment criteria:**

- Must be treated by a dermatologist.

A patient is eligible for re-treatment due to disease flare if:

(i) all subscores are rated moderate to severe or 2 of the 3 subscores are rated severe to very severe; or

(ii) the skin area affected is a 50% or greater change or the area affected is 30% or more of the face, palm of a hand or sole of a foot, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and
(b) a completed Severe Chronic Plaque Psoriasis in Patients Less Than 18 Years PBS Authority Application - Supporting Information which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area digrams including the dates of assessment of the patient’s condition; and

(ii) details of prior etanercept treatment, including date ceased.

Where a patient has had a treatment break the length of the break is measured from the date the most recent treatment was stopped to the date of the application for further treatment.

**Note**

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826
ETANERCEPT
Authority required
Severe active juvenile idiopathic arthritis
Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months)

Clinical criteria:
Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years,
AND
Patient must have received no PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition in the previous 24 months; OR
Patient must have received no PBS-subsidised bDMARD treatment for at least 5 years if they failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) in their last treatment cycle,
AND
Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR
Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR
Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above, must include at least 3 months continuous treatment with each of at least 2 DMARDs, with one or more of the following DMARDs being used in place of the DMARDs which are contraindicated or not tolerated: (i) azathioprine at a dose of at least 1 mg/kg per day; and/or (ii) cyclosporin at a dose of at least 2 mg/kg/day; and/or (iii) sodium aurothiomalate at a dose of 50 mg weekly,
AND
Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:
Patient must be aged 18 years or older.

Treatment criteria:
Must be treated by a rheumatologist; OR
Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

For the purposes of this restriction ‘biological disease modifying anti-rheumatic drug’ and ‘bDMARD’ mean adalimumab, etanercept or tocilizumab.

If methotrexate is contraindicated according to the TGA-approved Product Information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or...
ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance and dose for each DMARD must be provided in the authority application.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

(a) an active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form; and

(3) a signed patient acknowledgement.

If a patient fails to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle. A patient may re-trial etanercept after a minimum of 5 years have elapsed between the date of the last approval for PBS-subsidised bDMARD therapy in the last treatment cycle and the date of the first application under a new treatment cycle.

Note

The Department of Human Services website (www.humanservices.gov.au) has details of the toxicities, including severity, which will be accepted for the following purposes:

(a) exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose;

(b) substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial;

(c) exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy.

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Note

TREATMENT OF ADULT PATIENTS WITH A HISTORY OF JUVENILE IDIOPATHIC ARTHRITIS
A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 24 months may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 24 months must recommence treatment following a break in PBS-subsidised therapy. The length of the break in therapy is measured from the date the most recent treatment with PBS-subsidised bDMARD therapy was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or

(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or

(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised bDMARD following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

Where a response assessment is not submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. A patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count and ESR/CRP) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are
assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.

(4) Re-commencement of treatment after a 24 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 24 months, must requalify for treatment under the Initial 1 treatment restriction.

Authority required
Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after break of less than 24 months)

Clinical criteria:
Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years,

AND

Patient must have received prior PBS-subsidised treatment with adalimumab, etanercept or tocilizumab for this condition in this treatment cycle,

AND

Patient must not have failed PBS-subsidised therapy with etanercept for this condition in the current treatment cycle,

AND

Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:
Patient must be aged 18 years or older.

Treatment criteria:
Must be treated by a rheumatologist; OR
Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.

The authority application must be made in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

Applications for a patient who has received PBS-subsidised treatment with etanercept in this treatment cycle and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient’s most recent course of PBS-subsidised etanercept treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised etanercept treatment was approved under either of the Initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised etanercept treatment was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with etanercept.

If a patient fails to respond to PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;
AND either of the following:
(a) an active joint count of fewer than 10 active (swollen and tender) joints; or
(b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or
(c) a reduction in the number of the following active joints, from at least 4, by at least 50%:
   (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
   (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of
movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

**Note**

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

**Note**

**TREATMENT OF ADULT PATIENTS WITH A HISTORY OF JUVENILE IDIOPATHIC ARTHRITIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient over 18 years who has a history of juvenile idiopathic arthritis with onset prior to the age of 18 years. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.

From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 5 year break in PBS-subsidised bDMARD therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date of the last approval for PBS-subsidised bDMARD therapy in the last treatment cycle to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 24 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 24 months may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 24 months must commence a new treatment cycle. The length of the break in therapy is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or

(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or

(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

A patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to...
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count and ESR/CRP) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.

(4) Re-commencement of treatment after a 24 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 24 months, must requalify for treatment under the initial 1 treatment restriction.

**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months) or Initial 2 (change or recommencement of treatment after break of less than 24 months) – balance of supply

**Clinical criteria:**

Patient must have received insufficient etanercept therapy under the Initial 1 (new patient or patient recommencing treatment after break of more than 24 months) restriction to complete 16 weeks treatment; OR

Patient must have received insufficient etanercept therapy under the Initial 2 (change or recommencement of treatment after break of less than 24 months) restriction to complete 16 weeks treatment,

AND

The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Treatment criteria:**

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Note**

Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

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ETANERCEPT

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years,

AND

Patient must have demonstrated an adequate response to treatment with etanercept,

AND

Patient must have received etanercept as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment in this treatment cycle,

AND

Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

For the purposes of this restriction ‘biological disease modifying anti-rheumatic drug’ and ‘bDMARD’ mean adalimumab, etanercept or tocilizumab.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) an active joint count of fewer than 10 active (swollen and tender) joints; or
(b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or
(c) a reduction in the number of the following active joints, from at least 4, by at least 50%:
   (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
   (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

All applications for continuing treatment with etanercept must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with etanercept, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with etanercept.

If a patient fails to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle.

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
TREATMENT OF ADULT PATIENTS WITH A HISTORY OF JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient over 18 years who has a history of juvenile idiopathic arthritis with onset prior to the age of 18 years. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.

From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 5 year break in PBS-subsidised bDMARD therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date of the last approval for PBS-subsidised bDMARD therapy in the last treatment cycle to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 24 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 24 months may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 24 months must commence a new treatment cycle. The length of the break in therapy is measured from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count and ESR/CRP) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.

(4) Re-commencement of treatment after a 24 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 24 months, must requalify for treatment under the initial 1 treatment restriction.

**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment – balance of supply

**Clinical criteria:**

Patient must have received insufficient etanercept therapy under the Continuing treatment restriction to complete 24 weeks treatment, AND

The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Treatment criteria:**

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Note**

Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

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**ETANERCEPT**

**Authority required**

Active ankylosing spondylitis

Treatment Phase: Initial 1 (new patients)

**Clinical criteria:**

The condition must be radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis, AND

Patient must not have received any PBS-subsidised treatment with either adalimumab, certolizumab pegol, etanercept, golimumab or infliximab in this treatment cycle, AND
Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; or (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); or (iii) limitation of chest expansion relative to normal values for age and gender.

AND

Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months.

Population criteria:

Patient must be an adult.

Treatment criteria:

Must be treated by a rheumatologist.

The application must include details of the NSAIDs trialled, their doses and duration of treatment.

If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used.

If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication.

If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance.

The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application:

(a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; AND
(b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L.

The BASDAI must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. The BASDAI must be no more than 1 month old at the time of initial application.

Both ESR and CRP measures should be provided with the initial treatment application and both must be no more than 1 month old. If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and
(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form which must include the following:
(i) a copy of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and
(ii) a completed BASDAI Assessment Form; and
(iii) a completed Exercise Program Self Certification Form included in the supporting information form; and
(iv) a signed patient acknowledgment.

The assessment of the patient’s response to the initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted no later than 4 weeks from the cessation of that treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

A maximum of 16 weeks of treatment with this drug will be approved under this criterion.

Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) was approved in this cycle and the date of the first application under a new cycle.

Note
Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Department of Human Services website at www.humanservices.gov.au

Note
For details on the appropriate minimum exercise program that will be accepted for the purposes of administering this restriction, please refer to the Department of Human Services website at www.humanservices.gov.au

Note
No increase in the maximum quantity or number of units may be authorised.

Note
No increase in the maximum number of repeats may be authorised.

Authority required
Ankylosing spondylitis

Treatment Phase: Initial 2 (change or recommencement for all patients)

Clinical criteria:

Patient must have a documented history of active ankylosing spondylitis,
Patient must have received prior PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition in this treatment cycle,

AND

Patient must not have failed PBS-subsidised therapy with this drug for this condition in the current treatment cycle,

AND

Patient must be eligible to receive further bDMARD therapy.

Population criteria:
Patient must be an adult.

Treatment criteria:
Must be treated by a rheumatologist.

Where the most recent course of PBS-subsidised bDMARD treatment was approved under either of the initial treatment restrictions (i.e. for patients with no prior PBS-subsidised bDMARD therapy or, under this restriction, for patients who have received previous PBS-subsidised bDMARD therapy) the patient must have been assessed for response to that course following a minimum of 12 weeks of treatment. These assessments must be provided to the Department of Human Services no later than 4 weeks from the date the course was ceased. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, patients must have been assessed for response, and the assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

The authority application must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form.

A maximum of 16 weeks of treatment with this drug will be approved under this criterion.

Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised bDMARD was approved in this cycle and the date of the first application under a new cycle.

Note
No increase in the maximum quantity or number of units may be authorised.

Note
No increase in the maximum number of repeats may be authorised.

Note
Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs

Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Note
TREATMENT OF ADULT PATIENTS WITH ACTIVE ANKYLOSING SPONDYLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, certolizumab pegol, etanercept, golimumab and infliximab for adult patients with active ankylosing spondylitis.

Where the term ‘bDMARD’ appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 5 bDMARDs at any 1 time.

From 1 March 2007, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised bDMARDs without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a bDMARD while they continue to show a response to therapy.

A patient who received PBS-subsidised bDMARD treatment prior to 1 March 2007 is considered to be in their first cycle as of 1 March 2007.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once. A patient who, prior to 1 March 2007, was authorised to receive PBS-subsidised initial treatment for ankylosing spondylitis with the same agent twice, is exempt from this condition in respect of applications approved prior to 1 March 2007.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must...
have, at a minimum, a 5-year break in PBS-subsidised bDMARD therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised bDMARD treatment in the most recent cycle to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or

(iii) a patient wishes to re-commence treatment with a specific bDMARD following a break in PBS-subsidised therapy with that agent (Initial 2).

A patient must be assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI), or the prior NSAID therapy and exercise program requirements.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements.

For a new patient, the BASDAI used to determine the baseline must be measured while the patient is receiving NSAID therapy and completing their exercise program.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with at least 1 NSAID, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the BASDAI, ESR and/or CRP levels are measured.

**Authority required**

Ankylosing spondylitis

**Clinical criteria:**

Patient must have active, or a documented history of active, ankylosing spondylitis,
**ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS**

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**ETANERCEPT**

**Authority required**

Ankylosing spondylitis

Treatment Phase: Continuing treatment

**Clinical criteria:**

Patient must have a documented history of active ankylosing spondylitis,

AND

Patient must have received this drug as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment in this treatment cycle,

AND

Patient must have demonstrated an adequate response to treatment with this drug.

**Population criteria:**

Patient must be an adult.

**Treatment criteria:**

Must be treated by a rheumatologist.

An adequate response is defined as an improvement from baseline of at least 2 of the BASDAI and 1 of the following:

(a) an ESR measurement no greater than 25 mm per hour; or
(b) a CRP measurement no greater than 10 mg per L; or
(c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and supplied in all subsequent continuing treatment applications.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

Patient must have received insufficient therapy with this drug under the Initial 1 (new patients) restriction to complete 16 weeks treatment; OR

Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement for all patients) restriction to complete 16 weeks treatment,

AND

The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Population criteria:**

Patient must be an adult.

**Treatment criteria:**

Must be treated by a rheumatologist.

**Note**

No increase in the maximum number of repeats may be authorised.

**Note**

No increase in the maximum number of repeats may be authorised.

**Note**

Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001
A maximum of 24 weeks of treatment with this drug will be authorised under this criterion.

All applications for continuing treatment with this drug must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment following an initial treatment course it must be made following a minimum of 12 weeks of treatment with this drug. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-treat this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised bDMARD was approved in this cycle and the date of the first application under a new cycle.

Note
No increase in the maximum quantity or number of units may be authorised.

Note
No increase in the maximum number of repeats may be authorised.

Note
Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
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HOBART TAS 7001

Note
TREATMENT OF ADULT PATIENTS WITH ACTIVE ANKYLOSING SPONDYLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, certolizumab pegol, etanercept, golimumab and infliximab for adult patients with active ankylosing spondylitis.

Where the term ‘bDMARD’ appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 5 bDMARDs at any 1 time.

From 1 March 2007, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised bDMARDs without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a bDMARD while they continue to show a response to therapy.

A patient who received PBS-subsidised bDMARD treatment prior to 1 March 2007 is considered to be in their first cycle as of 1 March 2007.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once. A patient who, prior to 1 March 2007, was authorised to receive PBS-subsidised initial treatment for ankylosing spondylitis with the same agent twice, is exempt from this condition in respect of applications approved prior to 1 March 2007.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised bDMARD therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised bDMARD treatment in the most recent cycle to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
(ii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or
(iii) a patient wishes to re-commence treatment with a specific bDMARD following a break in PBS-subsidised therapy with that agent (Initial 2).

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and this
assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI), or the prior NSAID therapy and exercise program requirements.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements.

For a new patient, the BASDAI used to determine the baseline must be measured while the patient is receiving NSAID therapy and exercise program.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with at least 1 NSAID, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the BASDAI, ESR and/or CRP levels are measured.

**Authority required**

Ankylosing spondylitis

Treatment Phase: Continuing treatment – balance of supply

**Clinical criteria:**

Patient must have a documented history of active ankylosing spondylitis,

AND

Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment,

AND

The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Population criteria:**

Patient must be an adult.

**Treatment criteria:**

Must be treated by a rheumatologist.

**Note**

No increase in the maximum quantity or number of units may be authorised.

**Note**

No increase in the maximum number of repeats may be authorised.

**Note**

Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
**ETANERCEPT**

*Authority required*

Initial 1

Initial PBS-subsidised treatment with etanercept, by a rheumatologist or clinical immunologist with expertise in the management of psoriatic arthritis, of adults who:

1. have severe active psoriatic arthritis; and
2. have received no prior PBS-subsidised biological treatment for this condition in this Treatment Cycle; and
3. have failed to achieve an adequate response to:
   a. methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months; and
   b. sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; or
   c. leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity to necessitate permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of acceptable toxicities, including severity, can be found on the Medicare Australia website (www.medicareaustralia.gov.au).

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

- an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND
- either
  1. an active joint count of at least 20 active (swollen and tender) joints; or
  2. at least 4 active joints from the following list of major joints:
     - elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
     - shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:

1. a completed authority prescription form; and
2. a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and
3. a signed patient acknowledgement.

A maximum of 16 weeks treatment will be authorised under this restriction.

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

The assessment of the patient’s response to the initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Patients who fail to demonstrate a response to treatment with etanercept under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug, in this Treatment Cycle. Patients may re-trial etanercept after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle

*Authority required*
TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents (adalimumab, etanercept, golimumab and infliximab) for adult patients with severe active psoriatic arthritis.

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological agents at any 1 time. Where the term 'biological agents' appears in the following NOTES and restrictions, it only refers to adalimumab, etanercept, golimumab and infliximab.

From 1 August 2006, all patients will be able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

Following demonstration of response to initial treatment, these biological agents are available under the PBS for continuing treatment as set out in the continuing treatment restriction for each agent.

Once patients have either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological therapy before they are eligible to commence another Cycle [further details are under '(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' below].

The 5-year break in therapy will be measured from the date the last approval for PBS-subsidised treatment was granted in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Cycle.

Within the same Cycle, patients are not allowed to fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for any biological agent, they must change to an alternate agent which they have not previously failed, if they wish to continue PBS-subsidised biological treatment.

Patients for whom a break in PBS-subsidised therapy of less than 5 years has occurred, and, who have failed therapy fewer than 3 times within a 5-year period, must have, at a minimum, a 5-year break in PBS-subsidised therapy before they are eligible to recommence treatment (with etanercept) under the new Cycle. Therefore, patients who ceased PBS-subsidised etanercept treatment within a 5-year period after a break in PBS-subsidised therapy of more than 5 years will be deemed to have completed a single Cycle and must cease PBS-subsidised therapy for a minimum of 5 years before recommencing PBS-subsidised etanercept treatment.

The following arrangements apply to patients who wish to recommence PBS-subsidised therapy with etanercept.

Note: Where the most recent course of PBS-subsidised etanercept treatment was approved under the continuing treatment restriction, patients must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be provided to Medicare Australia no later than 4 weeks from the date that course was ceased.

Applications for patients who have received PBS-subsidised treatment with etanercept within this Treatment Cycle and who wish to recommence therapy with this drug within the same Cycle, must be accompanied by evidence of a response to the patient’s most recent course of PBS-subsidised etanercept treatment, within the timeframes specified below.

A maximum of 16 weeks treatment will be authorised under this restriction.

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Where the most recent course of PBS-subsidised etanercept treatment was approved under either of the initial treatment restrictions (i.e. for patients with no prior PBS-subsidised biological therapy or, under this restriction, for patients who have received previous PBS-subsidised biological therapy), patients must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be provided to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised etanercept treatment was approved under the continuing treatment criteria, patients must have been assessed for response, and the assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

The authority application must be made in writing and must include:

1. a completed authority prescription form; and
2. a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

Patients who fail to demonstrate a response to treatment with etanercept under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug, in this Treatment Cycle. Patients may re-trial etanercept after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

Note: Any queries concerning the arrangements to prescribe etanercept may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe etanercept should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

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<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
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<th>No. of Rpts</th>
<th>Premium $</th>
<th>Dispensed Price for Max. Qty $</th>
<th>Maximum Recordable Value for Safety Net $</th>
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<td>(2) have received prior PBS-subsidised biological treatment for this condition in this Treatment Cycle and are eligible to receive further biological therapy; and</td>
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<td>(3) have not failed treatment with etanercept during the current Treatment Cycle.</td>
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<td>Applications for patients who have received PBS-subsidised treatment with etanercept within this Treatment Cycle and who wish to re-commence therapy with this drug within this same Cycle, must be accompanied by evidence of a response to the patient’s most recent course of PBS-subsidised etanercept treatment, within the timeframes specified below.</td>
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particular treatment Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle.

There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe active psoriatic arthritis after 1 August 2010.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); and

(ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; and

(iii) patients wish to re-commence treatment with a specific biological agent following a break in PBS-subsidised therapy with that specific agent (Initial 3).

All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of therapy for all agents except for infliximab, for which a maximum of 22 weeks will be authorised. It is recommended that patients be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological agent supply.

Patients must be assessed for response to any course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

Grandfather patients — golimumab only.

Applications for patients who commenced treatment with golimumab prior to 1 March 2010 may apply for initial PBS-subsidised treatment as continuing therapy under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with any biological agent prior to PBS listing of that agent.

Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment for all agents. Approval will be based on the criteria included in the relevant restriction.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological agent, patients may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. Patients are eligible to receive continuing biological treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

Patients must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

(3) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate biological agent without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements.

Patients may swap to an alternate biological agent at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological agent at the time of the application or not.

Patients may alternate between therapy with any biological agent of their choice (1 at a time) providing:

(i) they have not received PBS-subsidised treatment with that particular biological agent previously; or

(ii) they have demonstrated an adequate response to that particular biological agent if they have previously trialled it on the PBS; or

(iii) they have not previously failed to respond to treatment 3 times in this Treatment Cycle.

To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the biological agent the patient is ceasing.

(4) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the indices of disease severity submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment authority is submitted within a treatment cycle and Medicare Australia will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

Patients who wish to trial a second or subsequent treatment Cycle following a break in PBS-subsidised biological therapy of at least 5 years, must
re-qualify for initial treatment with respect to both the indices of disease severity. Patients must have received treatment with methotrexate and sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured.

Note
No applications for increased maximum quantities and/or repeats will be authorised.

9457R  
ETANERCEPT Injection 50 mg in 1 mL single use auto-injector, 4, 1  
1 3 .. 1774.71 36.90 Enbrel PF

9087G  
ETANERCEPT Injections 50 mg in 1 mL single use pre-filled syringes, 4, 1  
1 3 .. 1774.71 36.90 Enbrel PF

9035M  
etanercept 25 mg injection [4 x 25 mg vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack  
2 3 .. *1774.70 36.90 Enbrel PF

ETANERCEPT
Authority required
Continuing treatment

Continuing PBS-subsidised treatment with etanercept, by a rheumatologist or clinical immunologist with expertise in the management of psoriatic arthritis, of adults:

(1) who have a documented history of severe active psoriatic arthritis; and

(2) whose most recent course of PBS-subsidised biological agent for this condition in the current Treatment Cycle was with etanercept; and

(3) who, at the time of application, demonstrate an adequate response to treatment with etanercept.

An adequate response to treatment with etanercept is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following:

(i) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(ii) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

— elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

— shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

A maximum of 24 weeks of treatment will be approved under this restriction.

Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

All applications for continuing treatment with etanercept must include a measurement of response to the prior course of therapy. This assessment must be provided to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with etanercept, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with the initial treatment course.

Patients who fail to demonstrate a response to treatment with etanercept under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug, in this Treatment Cycle. Patients may re-trial etanercept after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

Note
Any queries concerning the arrangements to prescribe etanercept may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe etanercept should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs

Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Note
TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents (adalimumab,
Patients are eligible for PBS-subsidised treatment with only 1 of the above biological agents at any 1 time. Where the term ‘biological agents’ appears in the following NOTES and restrictions, it only refers to adalimumab, etanercept, golimumab and infliximab.

From 1 August 2006, all patients will be able to commence a ‘Biological Treatment Cycle’ (Cycle), where they may trial biological agents without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

Following demonstration of response to initial treatment, these biological agents are available under the PBS for continuing treatment as set out in the continuing treatment restriction for each agent.

Once patients have either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological therapy before they are eligible to commence another Cycle [further details are under ‘(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy’ below].

The 5-year break in therapy will be measured from the date the last approval for PBS-subsidised treatment was granted in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Cycle.

Within the same Cycle, patients are not allowed to fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for any biological agent, they must change to an alternate agent which they have not previously failed, if they wish to continue PBS-subsidised biological treatment.

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle.

There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe active psoriatic arthritis after 1 August 2010.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); and

(ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; and

(iii) patients wish to re-commence treatment with a specific biological agent following a break in PBS-subsidised therapy with that specific agent (Initial 2).

All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of therapy for all agents except for infliximab, for which a maximum of 22 weeks will be authorised. It is recommended that patients be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological agent supply.

Patients must be assessed for response to any course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

Grandfather patients — golimumab only.

Applications for patients who commenced treatment with golimumab prior to 1 March 2010 may apply for initial PBS-subsidised treatment as continuing therapy under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with any biological agent prior to PBS listing of that agent.

Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment for all agents. Approval will be based on the criteria included in the relevant restriction.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological agent, patients may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. Patients are eligible to receive continuing biological treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

Patients must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

(3) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate biological agent without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements.

Patients may swap to an alternate biological agent at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological agent at the time of the application or not.

Patients may alternate between therapy with any biological agent of their choice (1 at a time) providing:

(i) they have not received PBS-subsidised treatment with that particular biological agent previously; or

(ii) they have demonstrated an adequate response to that particular biological agent if they have previously trialled it on the PBS; or
To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the biological agent the patient is ceasing.

(4) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the indices of disease severity submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment authority is submitted within a treatment Cycle and Medicare Australia will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

Patients who wish to trial a second or subsequent treatment Cycle following a break in PBS-subsidised biological therapy of at least years, must re-qualify for initial treatment with respect to both the indices of disease severity. Patients must have received treatment with methotrexate and sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured.

Note

No applications for increased maximum quantities and/or repeats will be authorised.

<table>
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<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
<th>Dispensed Price for Max. Qty $</th>
<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
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<td>5</td>
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</tbody>
</table>

ETANERCEPT

Authority required

Initial 1 (new patient or patient re-commencing after a break of more than 24 months)

Initial PBS-subsidised treatment with etanercept, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults who:

(a) have severe active rheumatoid arthritis; and
(b) have received no PBS-subsidised treatment with a bDMARD for this condition in the previous 24 months; and
(c) have failed, in the 24 months immediately prior to the date of application, to achieve an adequate response to at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs), which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be:

— hydroxychloroquine at a dose of at least 200 mg daily; or
— leflunomide at a dose of at least 10 mg daily; or
— sulfasalazine at a dose of at least 2 g daily.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, then the 6 months of intensive DMARD treatment must include at least 3 months continuous treatment with each of at least 2 of the DMARDs:

— hydroxychloroquine at a dose of at least 200 mg daily; and/or
— leflunomide at a dose of at least 10 mg daily; and/or
— sulfasalazine at a dose of at least 2 g daily.

The application must include details of the contraindication or intolerance to methotrexate. Details of the toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose can be found on the Medicare Australia website [www.medicareaustralia.gov.au]. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

If 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved product information or cannot be tolerated at the doses specified above, then one or more of the following DMARDs may be used in place of these agents in order to satisfy the requirement for a trial of 6 months of intensive DMARD therapy with at least 2 DMARDs taken continuously for at least 3 months each:

— azathioprine at a dose of at least 1 mg/kg per day; and/or
— cyclosporin at a dose of at least 2 mg/kg/day; and/or
— sodium aurothiomalate at a dose of 50 mg weekly.
The application must include details of the DMARDs trialed, their doses and duration of treatment, and all relevant contraindications and/or intolerances. Details of the toxicities, including severity, which will be accepted as a reason for substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial can be found on the Medicare Australia website [www.medicareaustralia.gov.au].

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance and dose for each DMARD must be provided in the authority application. Details of the toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy can be found on the Medicare Australia website [www.medicareaustralia.gov.au].

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

- an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either
  - (i) a total active joint count of at least 20 active (swollen and tender) joints; or
  - (ii) at least 4 active joints from the following list of major joints:
    - elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
    - shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and
- (3) a signed patient acknowledgement.

A maximum of 16 weeks of treatment will be authorised under this restriction.

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Assessment of a patient's response to an initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with etanercept.

Patients who fail to demonstrate a response to treatment with etanercept under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition

**Authority required**

Initial 2 (change or re-commencement after break of less than 24 months)

Initial course of PBS-subsidised treatment with etanercept, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults who:

- (a) have a documented history of severe active rheumatoid arthritis; and
- (b) have received prior PBS-subsidised bDMARD treatment for this condition and are eligible to receive further bDMARD therapy.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

Applications for patients who have received PBS-subsidised treatment with etanercept and who wish to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient’s most recent course of PBS-subsidised etanercept treatment, within the timeframes specified below.

A maximum of 16 weeks of treatment will be authorised under this restriction.
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying anti-rheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab) and the T-cell co-stimulation modulator (abatacept).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

PBS-subsidised abatacept, golimumab, infliximab and rituximab must be used in combination with methotrexate at a dose of at least 7.5 mg weekly. Where a patient cannot tolerate 7.5 mg of methotrexate weekly, they are eligible to receive PBS-subsidised adalimumab, certolizumab pegol, etanercept and tocilizumab.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:

- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe etanercept should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Note
TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying anti-rheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab) and the T-cell co-stimulation modulator (abatacept).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

PBS-subsidised abatacept, golimumab, infliximab and rituximab must be used in combination with methotrexate at a dose of at least 7.5 mg weekly. Where a patient cannot tolerate 7.5 mg of methotrexate weekly, they are eligible to receive PBS-subsidised adalimumab, certolizumab pegol, etanercept and tocilizumab.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:

- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact Medicare Australia on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs...
and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or

(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or

(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or

(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab and tocilizumab, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to Medicare Australia within 4 weeks. Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:

Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient’s weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:

A further application may be submitted to Medicare Australia 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialed.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the
time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept patients:

Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

Note
No applications for increased maximum quantities and/or repeats will be authorised.

Note
Special Pricing Arrangements apply.

9459W ETANERCEPT Injection 50 mg in 1 mL single use auto-injector, 4, 1

9089J ETANERCEPT Injections 50 mg in 1 mL single use pre-filled syringes, 4, 1

8637N etanercept 25 mg injection [4 x 25 mg vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack

ETANERCEPT
Authority required
Continuing treatment
Continuing PBS-subsidised treatment with etanercept, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults:

(a) who have a documented history of severe active rheumatoid arthritis; and

(b) who have demonstrated an adequate response to treatment with etanercept; and

(c) whose most recent course of PBS-subsidised bDMARD treatment was with etanercept.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following:

(i) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(ii) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

— elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

— shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

A maximum of 24 weeks of treatment will be approved under this restriction.

Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

All applications for continuing treatment with etanercept must include a measurement of response to the prior course of therapy. This assessment must be provided to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with etanercept, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

Patients who fail to demonstrate a response to treatment with etanercept under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further
restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists
rheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and
DMARD therapy.

HOBART TAS 7001

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-
for the treatment of rheumatoid arthritis.

— once a patient has either failed or ceas ed to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs
— a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must
etanercept and tocilizumab.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:
— a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
— a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact Medicare Australia on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent course of PBS-subsidised therapy was stopped to the
months must requalify for treatment under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction.

1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying anti-rheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 mononclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab) and the T-cell co-stimulation modulator (abatacept).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent course of PBS-subsidised therapy was stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.
(a) Initial treatment.

Applications for initial treatment should be made where:
(i) a patient has received prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and Medicare Australia will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Note
Any queries concerning the arrangements to prescribe etanercept may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe etanercept should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Note
TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying anti-rheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 mononclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab) and the T-cell co-stimulation modulator (abatacept).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

PBS-subsidised abatacept, golimumab, infliximab and rituximab must be used in combination with methotrexate at a dose of at least 7.5 mg weekly. Where a patient cannot tolerate 7.5 mg of methotrexate weekly, they are eligible to receive PBS-subsidised adalimumab, certolizumab pegol, etanercept and tocilizumab.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:
— a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
— a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact Medicare Australia on 1800 700 270.
Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

A patient may be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to Medicare Australia within 4 weeks.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:

Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient’s weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:

A further application may be submitted to Medicare Australia 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent course of treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate [ESR], the C-reactive protein [CRP] levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialed.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept patients:

Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify for treatment with that bDMARD must be reassessed to ensure they have demonstrated a response to any prior treatment.

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Details are under 'Swapping therapy' below; or

(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab and tocilizumab, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to Medicare Australia within 4 weeks.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:

Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:

A further application may be submitted to Medicare Australia 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent course with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate [ESR], the C-reactive protein [CRP] levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialed.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept patients:

Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify for treatment with that bDMARD must be reassessed to ensure they have demonstrated a response to any prior treatment.
and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

**Note**
No applications for increased maximum quantities and/or repeats will be authorised.

**Note**
Special Pricing Arrangements apply.

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**ETANERCEPT**

**Authority required**

Initial treatment [Initial 1, Whole body (New patients — No prior biological agent)]

Initial treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over who:

(a) have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis; and
(b) have not received any prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle; and
(c) have signed a patient and prescriber acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment (whole body); and
(d) have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 3 of the following 4 treatments:

(i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or
(ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; and/or
(iii) cyclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; and/or
(iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity to necessitate permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of acceptable toxicities including severity, associated with phototherapy, methotrexate, cyclosporin and acitretin, can be found on the Medicare Australia website (www.medicareaustralia.gov.au).

The following initiation criterion indicates failure to achieve an adequate response and must be demonstrated in all patients at the time of the application:

(a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 1 month old at the time of application.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and
(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient’s condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and
(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; and
(iii) the signed patient and prescriber acknowledgements.

A maximum of 16 weeks of treatment with etanercept will be authorised under this restriction.

Where fewer than 3 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period beyond 16 weeks.

A PASI assessment of the patient’s response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response
Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must

If intolerance to treatment develops during the relevant period of use, which is of a severity to necessitate permanent treatment withdrawal,

Phototherapy is contraindicated, please provide details at the time of application.

(a) have documented history of severe chronic plaque psoriasis; and

(b) have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle; and

(c) have not failed PBS-subsidised therapy with etanercept for the treatment of this condition in the current Treatment Cycle.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient’s condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and

(ii) details of prior biological treatment, including dosage, date and duration of treatment.

Applications for patients who have demonstrated a response to PBS-subsidised etanercept treatment within this Treatment Cycle and who wish to re-commence etanercept treatment within the same Cycle following a break in therapy, will only be approved where evidence of the patient’s response to their most recent course of PBS-subsidised etanercept treatment has been submitted to Medicare Australia within 1 month of cessation of treatment.

A maximum of 16 weeks of treatment with etanercept will be authorised under this restriction.

Where fewer than 3 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period beyond 16 weeks.

A PASI assessment of the patient’s response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with etanercept. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised etanercept treatment

**Authority required**

Initial or re-Treatment [Initial 2, Whole body (Received prior biological agent under PBS)]

Treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over who:

(a) have severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis; and

(b) have not received any prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle; and

(c) have failed to achieve adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 3 of the following 4 treatments:

(i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or

(ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; and/or

(iii) cyclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; and/or

(iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity to necessitate permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of acceptable toxicities including severity, associated with
The following initiation criterion indicates failure to achieve an adequate response and must be demonstrated in all patients at the time of the application:

(a) Chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:

(i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment; or

(ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 1 month old at the time of application.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient’s condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; and

(iii) the signed patient and prescriber acknowledgements.

A maximum of 16 weeks of treatment with etanercept will be authorised under this restriction.

Where fewer than 3 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period beyond 16 weeks.

A PASI assessment of the patient’s response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with etanercept. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current course of PBS-subsidised etanercept treatment. The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

**Authority required**

Initial or re-Treatment [Initial 2, Face, hand, foot (Received prior biological agent under PBS)]

Treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over who:

(a) have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot; and

(b) have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle; and

(c) have not failed PBS-subsidised treatment with etanercept for the treatment of this condition in the current Treatment Cycle.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient’s condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and

(ii) details of prior biological treatment, including dosage, date and duration of treatment.

Applications for patients who have demonstrated a response to PBS-subsidised etanercept treatment within this Treatment Cycle and who wish to re-commence etanercept treatment within the same Cycle following a break in therapy, will only be approved where evidence of the patient’s response to their most recent course of PBS-subsidised etanercept treatment has been submitted to Medicare Australia within 1 month of cessation of treatment.

A maximum of 16 weeks of treatment with etanercept will be authorised under this restriction.

Where fewer than 3 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period beyond 16 weeks.

A PASI assessment of the patient’s response to this course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response...
assessments is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with etanercept. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criteria for PBS-subsidised etanercept treatment.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may re-commence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle

Note
Any queries concerning the arrangements to prescribe etanercept may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe etanercept should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

Note
TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLACQUE PSORIASIS

The following applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, etanercept, infliximab and ustekinumab, for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological agents' appears in the following NOTES and restrictions, it only refers to adalimumab, etanercept, infliximab and ustekinumab.

From 1 March 2010, all patients will be able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial adalimumab, etanercept, infliximab or ustekinumab without having to meet the initial treatment criteria, that is they will not need to experience a disease flare when swapping to an alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

A patient who received PBS-subsidised biological agent treatment for chronic plaque psoriasis prior to 1 March 2010 is considered to be in their first Cycle as of 1 March 2010.

Patients are eligible for PBS-subsidised treatment with only 1 biological agent at any 1 time.

Within the same Treatment Cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for a PBS-subsidised biological agent, they must change to an alternate agent if they wish to continue PBS-subsidised biological treatment. A patient who, prior to 1 March 2010, was authorised to receive PBS-subsidised initial treatment for chronic plaque psoriasis with the same agent twice, is exempt from this condition in respect of applications approved prior to 1 March 2010.

Patients must be assessed for response to each course of continuing treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a Treatment Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological agent therapy before they are eligible to commence the next Cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological agent treatment in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Treatment Cycle.

Patients for whom a break in PBS-subsidised therapy of less than 5 years duration has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle.

There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe chronic plaque psoriasis after 1 March 2010.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Application for approval for initial treatment.

Applications for a course of initial treatment should be made in the following situations:

(i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); or

(ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under ‘(4) Swapping therapy’ below]; or

(iii) patients who wish to re-commence treatment following a break in PBS-subsidised therapy with that agent (Initial 2).

All applications for initial treatment will be limited to provide for a maximum of 16 weeks of treatment in the case of adalimumab and etanercept,
(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological agent, a PASI assessment must be conducted after at least 12 weeks of treatment. This assessment must be submitted to Medicare Australia within 1 month of the completion of this initial treatment course. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

(3) Application for continuing treatment.

Following the completion of an initial treatment course of a biological agent to which an adequate response has been demonstrated, patients may qualify to receive up to 24 weeks of continuing treatment with that biological agent. Patients are eligible to continue to receive continuous treatment with 24 week courses providing they continue to sustain a response.

For second and subsequent courses of PBS-subsidised treatment with adalimumab, etanercept, infliximab or ustekinumab it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Where a response assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to sustain a response to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

(4) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate agent within the same Treatment Cycle without having to requalify with respect to disease severity (i.e. a PASI score of greater than 15), or prior treatment requirements.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

Patients may trial an alternate biological agent at any time, regardless of whether they are receiving therapy with a biological agent at the time of the application or not. However, they cannot swap to a particular agent if they have failed to respond to treatment with that particular agent within the same Cycle.

Patients who commenced treatment with adalimumab prior to 1 June 2009 or ustekinumab prior to 1 March 2010 access these interchangeability arrangements in the same way as patients who have not.

To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the agent being ceased.

(5) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment authority is submitted within a Treatment Cycle and subsequent response will be assessed according to this revised PASI score.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatment applications.

(6) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

Patients who wish to trial a second or subsequent Biological Treatment Cycle, following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment according to the criteria of the relevant restriction and index of disease severity. Patients must have had at least 1 prior treatment, as listed in the criteria, for a minimum of 6 weeks, and must have a PASI assessment conducted preferably whilst still on treatment, but no later than 1 month following cessation of treatment. The PASI assessment must be no older than 1 month at the time of application.

**Note**

No applications for increased maximum quantities and/or repeats will be authorised.

**Note**

Special Pricing Arrangements apply.

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**ETANERCEPT**

**Authority required**

Continuing treatment (Whole body)
Continuing PBS-subsidised treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over:

(a) who have a documented history of severe chronic plaque psoriasis; and
(b) whose most recent course of PBS-subsidised biological treatment for this condition in this Treatment Cycle was with etanercept; and
(c) who have demonstrated an adequate response to their most recent course of treatment with etanercept.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, as compared to the pre-biological treatment baseline value for this Treatment Cycle.

This assessment must be provided to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with etanercept, the assessment of response must be after a minimum of 12 weeks of treatment with an initial course.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and
(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) the completed Psoriasis Area and Severity Index (PASI) calculation sheet along with the date of the assessment of the patient’s condition.
(ii) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the pre-biological treatment baseline values; or
(iii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the pre-biological treatment baseline value.

This assessment must be provided to Medicare Australia no later than 4 weeks from the cessation of the treatment course. If the application is the first application for continuing treatment with etanercept, the assessment of response must be after a minimum of 12 weeks of treatment with an initial course.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and
(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) the completed Psoriasis Area and Severity Index (PASI) calculation sheet along with the date of the assessment of the patient’s condition.
(ii) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the pre-biological treatment baseline values; or
(iii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the pre-biological treatment baseline value.

This assessment must be provided to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with etanercept, the assessment of response must be after a minimum of 12 weeks of treatment with an initial course.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and
(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) the completed Psoriasis Area and Severity Index (PASI) calculation sheet along with the date of the assessment of the patient’s condition.
(ii) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the pre-biological treatment baseline values; or
(iii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the pre-biological treatment baseline value.

This assessment must be provided to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with etanercept, the assessment of response must be after a minimum of 12 weeks of treatment with an initial course.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and
(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) the completed Psoriasis Area and Severity Index (PASI) calculation sheet along with the date of the assessment of the patient’s condition.
(ii) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the pre-biological treatment baseline values; or
(iii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the pre-biological treatment baseline value.

This assessment must be provided to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with etanercept, the assessment of response must be after a minimum of 12 weeks of treatment with an initial course.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and
(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) the completed Psoriasis Area and Severity Index (PASI) calculation sheet along with the date of the assessment of the patient’s condition.
(ii) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the pre-biological treatment baseline values; or
(iii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the pre-biological treatment baseline value.

This assessment must be provided to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with etanercept, the assessment of response must be after a minimum of 12 weeks of treatment with an initial course.
that would otherwise extend the treatment period beyond 24 weeks.

A PASI assessment of the patient’s response must be conducted within 4 weeks prior to completion of this course of treatment. This assessment must be submitted to Medicare Australia no later than 1 month from the date of completion of this course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with etanercept. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised etanercept treatment.

The PASI assessment for continuing treatment must be performed on the same affected area assessed at baseline.

Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may re-commence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

**Note**

Any queries concerning the arrangements to prescribe etanercept may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe etanercept should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

**Note**

**TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, etanercept, infliximab and ustekinumab, for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological agents' appears in the following NOTES and restrictions, it only refers to adalimumab, etanercept, infliximab and ustekinumab.

From 1 March 2010, all patients will be able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial adalimumab, etanercept, infliximab or ustekinumab without having to meet the initial treatment criteria, that is they will not need to experience a disease flare when swapping to an alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

A patient who received a PBS-subsidised biological agent treatment for chronic plaque psoriasis prior to 1 March 2010 is considered to be in their first Cycle as of 1 March 2010.

Patients are eligible for PBS-subsidised treatment with only 1 biological agent at any 1 time.

Within the same Treatment Cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for a PBS-subsidised biological agent, they must change to an alternate agent if they wish to continue PBS-subsidised biological treatment. A patient who, prior to 1 March 2010, was authorised to receive PBS-subsidised initial treatment for chronic plaque psoriasis with the same agent twice, is exempt from this condition in respect of applications approved prior to 1 March 2010.

Patients must be assessed for response to each course of continuing treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a Treatment Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological agent therapy before they are eligible to commence the next Cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological agent treatment in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Treatment Cycle.

Patients for whom a break in PBS-subsidised therapy of less than 5 years duration has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle.

There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe chronic plaque psoriasis after 1 March 2010.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Application for approval for initial treatment.

Applications for a course of initial treatment should be made in the following situations:

(i) patients have not received prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); or

(ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under ‘(4)’]
Patients may trial an alternate biological agent at any time, regardless of whether they are receiving therapy with a biological agent at the time of the application or not. However, they cannot swap to a particular agent if they have failed to respond to treatment with that particular agent within the same Cycle.

To ensure consistency in determining response, the same body area assessed at baseline must be assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the agent being ceased.

(5) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment authority is submitted

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatment applications.

(6) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

Patients who wish to trial a second or subsequent Biological Treatment Cycle, following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment according to the criteria of the relevant restriction and index of disease severity. Patients must have had at least 1 prior treatment, as listed in the criteria, for a minimum of 6 weeks, and must have a PASI assessment conducted preferably whilst still on treatment, but no later than 1 month following cessation of treatment. The PASI assessment must be no older than 1 month at the time of application.

Note

No applications for increased maximum quantities and/or repeats will be authorised.

Note

Special Pricing Arrangements apply.

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ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

GOLIMUMAB

Authority required

Initial PBS-subsidised treatment with golimumab, in combination with methotrexate at a dose of at least 7.5 mg weekly, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults who:

(a) have severe active rheumatoid arthritis; and
(b) have received no PBS-subsidised treatment with a bDMARD for this condition in the previous 24 months; and
(c) have failed, in the 24 months immediately prior to the date of application, to achieve an adequate response to at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs), which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be:

— hydroxychloroquine at a dose of at least 200 mg daily; or
— leflunomide at a dose of at least 10 mg daily; or
— sulfasalazine at a dose of at least 2 g daily.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, then the 6 months of intensive DMARD treatment must include at least 3 months continuous treatment with each of at least 2 of the DMARDs:

— hydroxychloroquine at a dose of at least 200 mg daily; and/or
— leflunomide at a dose of at least 10 mg daily; and/or
— sulfasalazine at a dose of at least 2 g daily.

The application must include details of the contraindication or intolerance to methotrexate. Details of the toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose can be found on the Medicare Australia website [www.medicareaustralia.gov.au]. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

If 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved product information or cannot be tolerated at the doses specified above, then one or more of the following DMARDs may be used in place of these agents in order to satisfy the requirement for a trial of 6 months of intensive DMARD therapy with at least 2 DMARDs taken continuously for at least 3 months each:

— azathioprine at a dose of at least 1 mg/kg per day; and/or
— cyclosporin at a dose of at least 2 mg/kg/day; and/or
— sodium aurothiomalate at a dose of 50 mg weekly.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances. Details of the toxicities, including severity, which will be accepted as a reason for substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial can be found on the Medicare Australia website [www.medicareaustralia.gov.au].

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance and dose for each DMARD must be provided in the authority application. Details of the toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy can be found on the Medicare Australia website [www.medicareaustralia.gov.au].

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

(i) a total active joint count of at least 20 active (swollen and tender) joints; or
(ii) at least 4 active joints from the following list of major joints:
— elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
— shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.
The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and

(3) a signed patient acknowledgement.

A maximum of 16 weeks of treatment will be authorised under this restriction.

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be required by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Assessment of a patient’s response to an initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with golimumab.

Patients who fail to demonstrate a response to treatment with golimumab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition

**Authority required**

Initial 2 (change or re-commencement after break of less than 24 months)

Initial course of PBS-subsidised treatment with golimumab, in combination with methotrexate at a dose of at least 7.5 mg weekly, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults who:

(a) have a documented history of severe active rheumatoid arthritis; and

(b) have received prior PBS-subsidised bDMARD treatment for this condition and are eligible to receive further bDMARD therapy.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

Applications for patients who have received PBS-subsidised treatment with golimumab and who wish to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient’s most recent course of PBS-subsidised golimumab treatment, within the timeframes specified below.

A maximum of 16 weeks of treatment will be authorised under this restriction.

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Where the most recent course of PBS-subsidised golimumab treatment was approved under either of the initial 1 or 2 treatment restrictions, patients must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be provided to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised golimumab treatment was approved under the continuing treatment criteria, patients must have been assessed for response, and the assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Patients who fail to demonstrate a response to treatment with golimumab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition

**Note**

(3) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and Medicare Australia will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

**Note**

Any queries concerning the arrangements to prescribe golimumab may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with details are under ‘Swapping therapy’ below; or

(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab) and the T-cell co-stimulation modulator (abatacept).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time. PBS-subsidised abatacept, golimumab, infliximab and rituximab must be used in combination with methotrexate at a dose of at least 7.5 mg weekly. Where a patient cannot tolerate 7.5 mg of methotrexate weekly, they are eligible to receive PBS-subsidised adalimumab, certolizumab pegol, etanercept and tocilizumab.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:

— a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,

— a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and

— once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact Medicare Australia on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or

(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or

(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or

(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab and tocilizumab. 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to Medicare Australia within 4 weeks.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to Medicare Australia no later than 2 weeks prior...
to the patient completing their current treatment course.

Abatacept patients:

Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient’s weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:

A further application may be submitted to Medicare Australia 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialed.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept patients:

Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

**Note**

Special Pricing Arrangements apply.

**GOLIMUMAB**

**Authority required**

Continuing treatment

Continuing PBS-subsidised treatment with golimumab, in combination with methotrexate at a dose of at least 7.5 mg weekly, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults:

(a) who have a documented history of severe active rheumatoid arthritis; and
A maximum of 24 weeks of treatment will be approved under this restriction. Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

All applications for continuing treatment with golimumab must include a measurement of response to the prior course of therapy. This assessment must be provided to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with golimumab, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

Patients who fail to demonstrate a response to treatment with golimumab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP. To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Any queries concerning the arrangements to prescribe golimumab may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe golimumab should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs

Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Note

TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying anti-rheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab) and the T-cell co-stimulation modulator (abatacept).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.
Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or

(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or

(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or

(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab and tocilizumab, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to Medicare Australia within 4 weeks.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:

Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient’s weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:

A further application may be submitted to Medicare Australia 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that

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ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>Safety Net $</th>
<th>Recordable Value for Max. Qty $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
</table>
|      | PBS-subsidised abatacept, golimumab, infliximab and rituximab must be used in combination with methotrexate at a dose of at least 7.5 mg weekly. Where a patient cannot tolerate 7.5 mg of methotrexate weekly, they are eligible to receive PBS-subsidised adalimumab, certolizumab pegol, etanercept and tocilizumab. In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist. A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements: — a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy, — a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and — once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis. For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact Medicare Australia on 1800 700 270. A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or

(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or

(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or

(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab and tocilizumab, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to Medicare Australia within 4 weeks.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:

Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient’s weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:

A further application may be submitted to Medicare Australia 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that
course was ceased.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate [ESR], the C-reactive protein [CRP] levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept patients:

Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

Note

Special Pricing Arrangements apply.

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<td>..</td>
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</tr>
</tbody>
</table>

GOLIMUMAB

Authority required

Initial 1

Initial PBS-subsidised treatment with golimumab, by a rheumatologist or clinical immunologist with expertise in the management of psoriatic arthritis, of adults who:

(1) have severe active psoriatic arthritis; and
(2) have received no prior PBS-subsidised biological treatment for this condition in this Treatment Cycle; and
(3) have failed to achieve an adequate response to:
(a) methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months; and
(b) sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; or
(c) leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity to necessitate permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of acceptable toxicities, including severity, can be found on the Medicare Australia website [www.medicareaustralia.gov.au].

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either
(i) an active joint count of at least 20 active (swollen and tender) joints; or
Prior Written Approval of Specialised Drugs

Initial PBS-subsidised treatment with golimumab, by a rheumatologist or clinical immunologist with expertise in the management of psoriatic arthritis, of adults who:

(1) have a documented history of severe active psoriatic arthritis; and

(2) have received prior PBS-subsidised biological treatment for this condition in this Treatment Cycle and are eligible to receive further biological therapy; and

(3) have not failed treatment with golimumab during the current Treatment Cycle.

Applications for patients who have received PBS-subsidised treatment with golimumab within this Treatment Cycle and who wish to re-commence therapy with this drug within this same Cycle, must be accompanied by evidence of a response to the patient’s most recent course of PBS-subsidised golimumab treatment, within the timeframes specified below.

A maximum of 16 weeks treatment will be authorised under this restriction.

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

The assessment of the patient’s response to the initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Patients who fail to demonstrate a response to treatment with golimumab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug, in this Treatment Cycle. Patients may re-trial golimumab after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

Authority required

Initial 2

Initial PBS-subsidised treatment with golimumab, by a rheumatologist or clinical immunologist with expertise in the management of psoriatic arthritis, of adults who:

(1) have a documented history of severe active psoriatic arthritis; and

(2) have received prior PBS-subsidised biological treatment for this condition in this Treatment Cycle and are eligible to receive further biological therapy; and

(3) have not failed treatment with golimumab during the current Treatment Cycle.

Applications for patients who have received PBS-subsidised treatment with golimumab within this Treatment Cycle and who wish to re-commence therapy with this drug within this same Cycle, must be accompanied by evidence of a response to the patient’s most recent course of PBS-subsidised golimumab treatment, within the timeframes specified below.

A maximum of 16 weeks treatment will be authorised under this restriction.

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

The assessment of the patient’s response to the initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Patients who fail to demonstrate a response to treatment with golimumab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug, in this Treatment Cycle. Patients may re-trial golimumab after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

Note

Any queries concerning the arrangements to prescribe golimumab may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe golimumab should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs
The 5-year break in therapy will be measured from the date the last approval for PBS-subsidised therapy and wish to trial an alternate agent following a break in PBS-subsidised therapy with that specific agent (Initial 2)

All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of therapy for all agents except for infliximab, for which a maximum of 22 weeks will be authorised. It is recommended that patients be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological agent supply. Patients must be assessed for response to any course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent. Grandfather patients — golimumab only.

Applications for patients who commenced treatment with golimumab prior to 1 March 2010 may apply for initial PBS-subsidised treatment as continuing therapy under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with any biological agent prior to PBS listing of that agent. Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment for all agents. Approval will be based on the criteria included in the relevant restriction.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological agent, patients may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. Patients are eligible to receive continuing biological treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. Patients must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

(3) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate biological agent without having to re-qualify with respect to either of the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein...
Patients may swap to an alternate biological agent at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological agent at the time of the application or not.

Patients may alternate between therapy with any biological agent of their choice (1 at a time) providing:

(i) they have not received PBS-subsidised treatment with that particular biological agent previously; or
(ii) they have demonstrated an adequate response to that particular biological agent if they have previously trialled it on the PBS; or
(iii) they have not previously failed to respond to treatment 3 times in this Treatment Cycle.

To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the biological agent the patient is ceasing.

(4) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the indices of disease severity submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment authority is submitted within a treatment Cycle and Medicare Australia will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

Patients who wish to trial a second or subsequent treatment Cycle following a break in PBS-subsidised biological therapy of at least 5 years, must re-qualify for initial treatment with respect to both the indices of disease severity. Patients must have received treatment with methotrexate and sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured.

Note

No applications for increased maximum quantities and/or repeats will be authorised. Applications for treatment with golimumab where the dosing frequency exceeds 50 mg every 4 weeks will not be approved.

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
<th>Dispensed Price for Max. Qty $</th>
<th>Premium $</th>
<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
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<td>1777.63</td>
<td>36.90</td>
<td></td>
<td>Simponi JC</td>
</tr>
</tbody>
</table>

GOLIMUMAB

Authority required

Initial 3 — grandfather golimumab patients

Initial PBS-subsidised supply for continuing treatment with golimumab, by a rheumatologist or clinical immunologist with expertise in the management of psoriatic arthritis, of adults who:

(1) have a documented history of severe active psoriatic arthritis; and
(2) were receiving treatment with golimumab prior to 1 March 2010; and
(3) have demonstrated a response as specified in the criteria for continuing PBS-subsidised treatment with golimumab; and
(4) are receiving treatment with golimumab at the time of application.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and
(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and
(3) a signed patient acknowledgement.

A maximum of 24 weeks of treatment with golimumab will be authorised under this restriction.

Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Patients who fail to demonstrate a response to treatment with golimumab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug, in this Treatment Cycle. Patients may re-trial golimumab after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

Patients may qualify for PBS-subsidised treatment under this restriction once only

Authority required

Continuing treatment
The 5-year break in therapy will be measured from the date the last approval for PBS-subsidised treatment was granted in the most recent Cycle to the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

All applications for continuing treatment with golimumab must include a measurement of response to the prior course of treatment within the previous Cycle. Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

All applications for continuing treatment with golimumab must include a measurement of response to the prior course of treatment. This assessment must be provided to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with golimumab, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with the initial treatment course.

Patients who fail to demonstrate a response to treatment with golimumab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug, in this Treatment Cycle. Patients may re-trial golimumab after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

**Note**

Any queries concerning the arrangements to prescribe golimumab may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe golimumab should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

**Note**

**TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents (adalimumab, etanercept, golimumab and infliximab) for adult patients with severe active psoriatic arthritis.

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological agents at any 1 time. Where the term ‘biological agents’ appears in the following NOTES and restrictions, it only refers to adalimumab, etanercept, golimumab and infliximab.

From 1 August 2006, all patients will be able to commence a ‘Biological Treatment Cycle’ (Cycle), where they may trial biological agents without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

Following demonstration of response to initial treatment, these biological agents are available under the PBS for continuing treatment as set out in the continuing treatment restriction for each agent.

Once patients have either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological therapy before they are eligible to commence another Cycle [further details are under ‘(S) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy’ below].

The 5-year break in therapy will be measured from the date the last approval for PBS-subsidised treatment was granted in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Cycle.

Within the same Cycle, patients are not allowed to fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for any biological agent, they must change to an alternate agent which they have not previously failed, if they wish to continue PBS-subsidised biological treatment.
To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe active psoriatic arthritis after 1 August 2010.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); and

(ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; and

(iii) patients wish to re-commence treatment with a specific biological agent following a break in PBS-subsidised therapy with that specific agent (Initial 2).

All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of therapy for all agents except for infliximab, for which a maximum of 22 weeks will be authorised. It is recommended that patients be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological agent supply.

Patients must be assessed for response to any course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

Grandfather patients — golimumab only.

Applications for patients who commenced treatment with golimumab prior to 1 March 2010 may apply for initial PBS-subsidised treatment as continuing therapy under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with any biological agent prior to PBS listing of that agent.

Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment for all agents. Approval will be based on the criteria included in the relevant restriction.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological agent, patients may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. Patients are eligible to receive continuing biological treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

Patients must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

(3) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate biological agent without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements.

Patients may swap to an alternate biological agent at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological agent at the time of the application or not.

Patients may alternate between therapy with any biological agent of their choice (1 at a time) providing:

(i) they have not received PBS-subsidised treatment with that particular biological agent previously; or

(ii) they have demonstrated an adequate response to that particular biological agent if they have previously trialled it on the PBS; or

(iii) they have not previously failed to respond to treatment 3 times in this Treatment Cycle.

To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the biological agent the patient is ceasing.

(4) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the indices of disease severity submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment authority is submitted within a treatment Cycle and Medicare Australia will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.
Patients who wish to trial a second or subsequent treatment Cycle following a break in PBS-subsidised biological therapy of at least 5 years, must re-qualify for initial treatment with respect to both the indices of disease severity. Patients must have received treatment with methotrexate and sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured.

Note
No applications for increased maximum quantities and/or repeats will be authorised. Applications for treatment with golimumab where the dosing frequency exceeds 50 mg every 4 weeks will not be approved.

3432P  
golimumab 50 mg/0.5 mL injection, 1 x 0.5 mL syringe  
1 5 .. 1777.63 36.90 Simponi JC

3433Q  
golimumab 50 mg/0.5 mL injection, 1 x 0.5 mL syringe  
1 5 .. 1777.63 36.90 Simponi JC

GOLIMUMAB

Authority required
Active ankylosing spondylitis
Treatment Phase: Initial 1 (new patients)

Clinical criteria:
The condition must be radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis,

AND
Patient must not have received any PBS-subsidised treatment with either adalimumab, certolizumab pegol, etanercept, golimumab or infliximab in this treatment cycle,

AND
Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; or (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); or (iii) limitation of chest expansion relative to normal values for age and gender,

AND
Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months.

Population criteria:
Patient must be an adult.

Treatment criteria:
Must be treated by a rheumatologist.
The application must include details of the NSAIDs trialled, their doses and duration of treatment.
If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used.
If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication.
If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance.
The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application:
(a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0–10 scale; AND
(b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L.
The BASDAI must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. The BASDAI must be no more than 1 month old at the time of initial application.
Both ESR and CRP measures should be provided with the initial treatment application and both must be no more than 1 month old. If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied.
The authority application must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form which must include the following:
(i) a copy of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and
(ii) a completed BASDAI Assessment Form; and
(iii) a completed Exercise Program Self Certification Form included in the supporting information form; and
(iv) a signed patient acknowledgment.
The assessment of the patient’s response to the initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted no later than 4 weeks from the cessation of that treatment course. If the response assessment is not submitted within these timeframes,
<table>
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</tr>
</thead>
</table>

The patient will be deemed to have failed this course of treatment.

A maximum of 16 weeks of treatment with this drug will be approved under this criterion.

Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) was approved in this cycle and the date of the first application under a new cycle.

**Note**
Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Department of Human Services website at www.humanservices.gov.au

**Note**
For details on the appropriate minimum exercise program that will be accepted for the purposes of administering this restriction, please refer to the Department of Human Services website at www.humanservices.gov.au

**Note**
No increase in the maximum quantity or number of units may be authorised.

**Note**
No increase in the maximum number of repeats may be authorised.

**Authority required**
Ankylosing spondylitis

Treatment Phase: Initial 2 (change or recommencement for all patients)

**Clinical criteria:**
Patient must have a documented history of active ankylosing spondylitis,

AND

Patient must have received prior PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition in this treatment cycle,

AND

Patient must not have failed PBS-subsidised therapy with this drug for this condition in the current treatment cycle,

AND

Patient must be eligible to receive further bDMARD therapy.

**Population criteria:**
Patient must be an adult.

**Treatment criteria:**
Must be treated by a rheumatologist.

Where the most recent course of PBS-subsidised bDMARD treatment was approved under either of the initial treatment restrictions (i.e. for patients with no prior PBS-subsidised bDMARD therapy or, under this restriction, for patients who have received previous PBS-subsidised bDMARD therapy) the patient must have been assessed for response to that course following a minimum of 12 weeks of treatment. These assessments must be provided to the Department of Human Services no later than 4 weeks from the date the course was ceased. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, patients must have been assessed for response, and the assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form.

A maximum of 16 weeks of treatment with this drug will be approved under this criterion.

Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised bDMARD was approved in this cycle and the date of the first application under a new cycle.

**Note**
No increase in the maximum quantity or number of units may be authorised.

**Note**
No increase in the maximum number of repeats may be authorised.

**Note**
Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, certolizumab pegol, etanercept, golimumab and infliximab for adult patients with active ankylosing spondylitis.

A patient is eligible for PBS-subsidised treatment with only 1 of the 5 bDMARDs at any 1 time. Where the term ‘bDMARD’ appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab and infliximab only.

A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of less than 5 years, may commence a treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI), or the prior NSAID therapy and exercise program requirements.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised bDMARD therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised bDMARD treatment in the most recent cycle to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or

(iii) a patient wishes to re-commence treatment with a specific bDMARD following a break in PBS-subsidised therapy with that agent (Initial 2).

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current course of treatment.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised bDMARD therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised bDMARD treatment in the most recent cycle to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or

(iii) a patient wishes to re-commence treatment with a specific bDMARD following a break in PBS-subsidised therapy with that agent (Initial 2).

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI), or the prior NSAID therapy and exercise program requirements.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are...
assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements.

For a new patient, the BASDAI used to determine the baseline must be measured while the patient is receiving NSAID therapy and completing their exercise program.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with at least 1 NSAID, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the BASDAI, ESR and/or CRP levels are measured.

Authority required

Ankylosing spondylitis

Treatment Phase: Initial treatment – Initial 1 (new patients) or Initial 2 (change or recommencement for all patients) – balance of supply

Clinical criteria:

Patient must have active, or a documented history of active, ankylosing spondylitis,

AND

Patient must have received insufficient therapy with this drug under the Initial 1 (new patients) restriction to complete 16 weeks treatment; OR

Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement for all patients) restriction to complete 16 weeks treatment,

AND

The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Population criteria:

Patient must be an adult.

Treatment criteria:

Must be treated by a rheumatologist.

Note

No increase in the maximum quantity or number of units may be authorised.

Note

No increase in the maximum number of repeats may be authorised.

Note

Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

3434R
golimumab 50 mg/0.5 mL injection, 1 x 0.5 mL syringe

1 3.. 1777.63 36.90 Simponi JC

3435T
golimumab 50 mg/0.5 mL injection, 1 x 0.5 mL syringe

1 3.. 1777.63 36.90 Simponi JC

GOLIMUMAB

Authority required

Ankylosing spondylitis

Treatment Phase: Continuing treatment

Clinical criteria:
Patient must have a documented history of active ankylosing spondylitis,
AND
Patient must have received this drug as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment in this treatment cycle,
AND
Patient must have demonstrated an adequate response to treatment with this drug.

**Population criteria:**
Patient must be an adult.

**Treatment criteria:**
Must be treated by a rheumatologist.
An adequate response is defined as an improvement from baseline of at least 2 of the BASDAI and 1 of the following:
(a) an ESR measurement no greater than 25 mm per hour; or
(b) a CRP measurement no greater than 10 mg per L; or
(c) an ESR or CRP measurement reduced by at least 20% from baseline.
Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and supplied in all subsequent continuing treatment applications.
The authority application must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form.
All measurements provided must be no more than 1 month old at the time of application.
A maximum of 24 weeks of treatment with this drug will be authorised under this criterion.
All applications for continuing treatment with this drug must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment following an initial treatment course it must be made following a minimum of 12 weeks of treatment with this drug. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.
Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised bDMARD was approved in this cycle and the date of the first application under a new cycle.

**Note**
No increase in the maximum quantity or number of units may be authorised.

**Note**
No increase in the maximum number of repeats may be authorised.

**Note**
Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

**Note**
**TREATMENT OF ADULT PATIENTS WITH ACTIVE ANKYLOSING SPONDYLITIS**
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, certolizumab pegol, etanercept, golimumab and infliximab for adult patients with active ankylosing spondylitis.
Where the term 'bDMARD' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab and infliximab only.
A patient is eligible for PBS-subsidised treatment with only 1 of the 5 bDMARDs at any 1 time.
From 1 March 2007, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised bDMARDs without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a bDMARD while they continue to show a response to therapy.
A patient who received PBS-subsidised bDMARD treatment prior to 1 March 2007 is considered to be in their first cycle as of 1 March 2007.
Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once. A
patient who, prior to 1 March 2007, was authorised to receive PBS-subsidised initial treatment for ankylosing spondylitis with the same agent twice, is exempt from this condition in respect of applications approved prior to 1 March 2007.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised bDMARD therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised bDMARD treatment in the most recent cycle to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or

(iii) a patient wishes to re-commence treatment with a specific bDMARD following a break in PBS-subsidised therapy with that agent (Initial 2).

A patient must be assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current course of treatment.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI), or the prior NSAID therapy and exercise program requirements.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements.

For a new patient, the BASDAI used to determine the baseline must be measured while the patient is receiving NSAID therapy and completing their exercise program.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with at least 1 NSAID, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the BASDAI, ESR and/or CRP levels are measured.

**Authority required**

Ankylosing spondylitis
### ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

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<th>No. of Rpts</th>
<th>Dispensed Price for Max. Qty $</th>
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### Interleukin inhibitors

**USTEKINUMAB**

**Authority required**

Initial treatment [Initial 1, Whole body (New patients — No prior biological agent)]

Initial treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over who:

(a) have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis; and

(b) have not received any prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle; and

(c) have signed a patient and prescriber acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment (whole body); and

(d) have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 3 of the following 4 treatments:

(i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or

(ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; and/or

(iii) cyclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; and/or

(iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity to necessitate permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of acceptable toxicities including severity, associated with phototherapy, methotrexate, cyclosporin and acitretin, can be found on the Medicare Australia website (www.medicareaustralia.gov.au).

The following initiation criteria indicates failure to achieve an adequate response and must be demonstrated in all patients at the time of the application:

(a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month...
following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 1 month old at the time of application.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient’s condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; and

(iii) the signed patient and prescriber acknowledgements.

A maximum of 28 weeks of treatment with ustekinumab will be authorised under this restriction. At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single injection. Up to a maximum of 2 repeats will be authorised.

Where fewer than 2 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 28 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period beyond 28 weeks.

A PASI assessment of the patient’s response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with ustekinumab. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised ustekinumab treatment

**Authority required**

Initial or re-Treatment [Initial 2, Whole body (Received prior biological agent under PBS)]

Treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over who:

(a) have a documented history of severe chronic plaque psoriasis; and

(b) have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle; and

(c) have not failed PBS-subsidised therapy with ustekinumab for the treatment of this condition in the current Treatment Cycle.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient’s condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and

(ii) details of prior biological treatment, including dosage, date and duration of treatment.

Applications for patients who have demonstrated a response to PBS-subsidised ustekinumab treatment within this Treatment Cycle and who wish to re-commence ustekinumab treatment within the same Cycle following a break in therapy, will only be approved where evidence of the patient’s response to their most recent course of PBS-subsidised ustekinumab treatment has been submitted to Medicare Australia within 1 month of cessation of treatment.

A maximum of 28 weeks of treatment with ustekinumab will be authorised under this restriction.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single injection. Up to a maximum of 2 repeats will be authorised.

Where fewer than 2 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 28 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period beyond 28 weeks.

A PASI assessment of the patient’s response to this course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with ustekinumab. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised ustekinumab treatment.

Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must...
Authority required

Initial treatment [Initial 1, Face, hand, foot (New patients — No prior biological agent)]

Initial treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over who:

(a) have severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis; and

(b) have not received any prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle; and

(c) have signed a patient and prescriber acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment (face, hand, foot); and

(d) have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 3 of the following 4 treatments:

(i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or

(ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; and/or

(iii) cyclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; and/or

(iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity to necessitate permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of acceptable toxicities including severity, associated with phototherapy, methotrexate, cyclosporin and acitretin, can be found on the Medicare Australia website (www.medicareaustralia.gov.au).

The following initiation criterion indicates failure to achieve an adequate response and must be demonstrated in all patients at the time of the application:

(a) Chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:

(i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment; or

(ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 1 month old at the time of application.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient’s condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; and

(iii) the signed patient and prescriber acknowledgements.

A maximum of 28 weeks of treatment with ustekinumab will be authorised under this restriction.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single injection. Up to a maximum of 2 repeats will be authorised.

Where fewer than 2 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 28 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period beyond 28 weeks.

A PASI assessment of the patient’s response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with ustekinumab. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised ustekinumab treatment.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.
Antineoplastic and immunomodulating agents

**Authority required**

Initial or re-treatment

(a) have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot; and

(b) have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle; and

(c) have not failed PBS-subsidised therapy with ustekinumab for the treatment of this condition in the current Treatment Cycle.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and

(ii) details of prior biological treatment, including dosage, date and duration of treatment.

Applications for patients who have demonstrated a response to PBS-subsidised ustekinumab treatment within this Treatment Cycle and who wish to re-commence ustekinumab treatment within the same Cycle following a break in therapy, will only be approved where evidence of the patient's response to their most recent course of PBS-subsidised ustekinumab treatment has been submitted to Medicare Australia within 1 month of cessation of treatment.

A maximum of 28 weeks of treatment with ustekinumab will be authorised under this restriction.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single injection. Up to a maximum of 2 repeats will be authorised.

Where fewer than 2 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 28 weeks of treatment may be requested by telephone contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period beyond 28 weeks.

A PASI assessment of the patient's response to this course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with ustekinumab. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised ustekinumab treatment.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may re-commence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

**Note**

Any queries concerning the arrangements to prescribe ustekinumab may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe ustekinumab should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

**TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, etanercept, infliximab and ustekinumab, for adult patients with severe chronic plaque psoriasis. Therefore, where the term ‘biological agents’ appears in the following NOTES and restrictions, it only refers to adalimumab, etanercept, infliximab and ustekinumab.

From 1 March 2010, all patients will be able to commence a ‘Biological Treatment Cycle’ (Cycle), where they may trial adalimumab, etanercept, infliximab or ustekinumab without having to meet the initial treatment criteria, that is they will not need to experience a disease flare when swapping to an alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

A patient who received PBS-subsidised biological agent treatment for chronic plaque psoriasis prior to 1 March 2010 is considered to be in their first Cycle as of 1 March 2010.
When prescribing initial treatment with a biological agent, a PASI assessment must be conducted after at least 12 weeks of treatment. This assessment of response to initial treatment must be submitted to Medicare Australia within 1 month of the completion of this initial treatment course. Where a response assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to sustain a response to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

For second and subsequent courses of PBS-subsidised treatment with adalimumab, etanercept, infliximab or ustekinumab it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course. Where a response assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to sustain a response to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

(4) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate agent within the same Treatment Cycle without having to requalify with respect to disease severity (i.e. a PASI score of greater than 15), or prior treatment requirements. Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

Patients who commenced treatment with adalimumab prior to 1 June 2009 or ustekinumab prior to 1 March 2010 access these interchangeability arrangements in the same way as patients who have not.

To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority...
(5) Baseline measurements to determine response. Medicare Australia will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment authority is submitted within a Treatment Cycle and subsequent response will be assessed according to this revised PASI score.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatment applications.

(6) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

Patients who wish to trial a second or subsequent Biological Treatment Cycle, following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment according to the criteria of the relevant restriction and index of disease severity. Patients must have had at least 1 prior treatment, as listed in the criteria, for a minimum of 6 weeks, and must have a PASI assessment conducted preferably whilst still on treatment, but no later than 1 month following cessation of treatment. The PASI assessment must be no older than 1 month at the time of application.

Note
No applications for increased repeats will be authorised.

UTEKINUMAB

Authority required

Continuing treatment (Whole body)

Continuing PBS-subsidised treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over:

(a) who have a documented history of severe chronic plaque psoriasis; and

(b) whose most recent course of PBS-subsidised biological treatment for this condition in this Treatment Cycle was with ustekinumab; and

(c) who have demonstrated an adequate response to their most recent course of treatment with ustekinumab.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the pre-treatment baseline value for this Treatment Cycle.

To ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised ustekinumab treatment.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) the completed Psoriasis Area and Severity Index (PASI) calculation sheet along with the date of the assessment of the patient’s condition.

The most recent PASI assessment must be no more than 1 month old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with ustekinumab.

A maximum of 24 weeks of treatment with ustekinumab will be authorised under this restriction.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single injection. Up to a maximum of 1 repeat will be authorised.

Where fewer than 1 repeat is requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for continuing authority applications, or for treatment that would otherwise extend the treatment period beyond 24 weeks.

A PASI assessment of the patient’s response must be conducted within 4 weeks prior to completion of this course of treatment. This assessment, which will be used to determine eligibility for further continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with ustekinumab. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised ustekinumab treatment.

Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may re-commence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.
TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS

Any queries concerning the arrangements to prescribe ustekinumab may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe ustekinumab should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Note

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, etanercept, infliximab and ustekinumab, for adult patients with severe chronic plaque psoriasis. Therefore, where the term ‘biological agents’ appears in the following NOTES and restrictions, it only refers to adalimumab, etanercept, infliximab and ustekinumab.

From 1 March 2010, all patients will be able to commence a ‘Biological Treatment Cycle’ (Cycle), where they may trial adalimumab, etanercept, infliximab or ustekinumab without having to meet the initial treatment criteria, that is they will not need to experience a disease flare when swapping to an alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with

Antineoplastic and Immunomodulating Agents

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
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<th>Premium $</th>
<th>Dispensed Price for Max. Qty $</th>
<th>Maximum Recordable Value for Safety Net $</th>
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</tr>
</thead>
</table>

**Authority required**

Continuing treatment (Face, hand, foot)

Continuing PBS-subsidised treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over:

(a) who have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot; and

(b) whose most recent course of PBS-subsidised biological treatment for this condition in this Treatment Cycle was with ustekinumab; and

(c) who have demonstrated an adequate response to treatment with ustekinumab.

An adequate response to ustekinumab treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the pre-biological treatment baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the pre-biological treatment baseline value.

This assessment must be provided to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with ustekinumab, the assessment of response must be after a minimum of 12 weeks of treatment with an initial course.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams along with the date of the

(ii) the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams along with the date of the assessment of the patient’s condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

The most recent PASI assessment must be no more than 1 month old at the time of application.

A maximum of 24 weeks of treatment with ustekinumab will be authorised under this restriction.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single injection. Up to a maximum of 1 repeat will be authorised.

Where fewer than 1 repeat is requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for continuing authority applications, or for treatment that would otherwise extend the treatment period beyond 24 weeks.

A PASI assessment of the patient’s response must be conducted within 4 weeks prior to completion of this course of treatment. This assessment, which will be used to determine eligibility for further continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with ustekinumab. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised ustekinumab treatment.

The PASI assessment for continuing treatment must be performed on the same affected area assessed at baseline.

Patients who fail to demonstrate a response to treatment with 2 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may re-commence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

**Note**

**TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, etanercept, infliximab and ustekinumab, for adult patients with severe chronic plaque psoriasis. Therefore, where the term ‘biological agents’ appears in the following NOTES and restrictions, it only refers to adalimumab, etanercept, infliximab and ustekinumab.

From 1 March 2010, all patients will be able to commence a ‘Biological Treatment Cycle’ (Cycle), where they may trial adalimumab, etanercept, infliximab or ustekinumab without having to meet the initial treatment criteria, that is they will not need to experience a disease flare when swapping to an alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with...
Patients are eligible for PBS-subsidised treatment with only 1 biological agent at any 1 time.

Within the same Treatment Cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for a PBS-subsidised biological agent, they must change to an alternate agent if they wish to continue PBS-subsidised biological treatment. A patient who, prior to 1 March 2010, was authorised to receive PBS-subsidised initial treatment for chronic plaque psoriasis with the same agent twice, is exempt from this condition in respect of applications approved prior to 1 March 2010.

Patients must be assessed for response to each course of continuing treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a Treatment Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological agent therapy before they are eligible to commence the next Cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological agent treatment in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Treatment Cycle.

Patients for whom a break in PBS-subsidised therapy of less than 5 years duration has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle.

There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe chronic plaque psoriasis after 1 March 2010.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Application for approval for initial treatment.

Applications for a course of initial treatment should be made in the following situations:

(i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); or

(ii) patients have received prior PBS-subsidised biological treatment and wish to trial an alternate agent (Initial 2) [further details are under ‘(4) Swapping therapy’ below]; or

(iii) patients who wish to re-commence treatment following a break in PBS-subsidised therapy with that agent (Initial 2).

All applications for initial treatment will be limited to provide for a maximum of 16 weeks of treatment in the case of adalimumab and etanercept, 22 weeks of treatment in the case of infliximab and 28 weeks of treatment in the case of ustekinumab.

(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological agent, a PASI assessment must be conducted after at least 12 weeks of treatment. This assessment must be submitted to Medicare Australia within 1 month of the completion of this initial treatment course. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

(3) Application for continuing treatment.

Following the completion of an initial treatment course of a biological agent to which an adequate response has been demonstrated, patients may qualify to receive up to 24 weeks of continuing treatment with that biological agent. Patients are eligible to continue to receive continuous treatment with 24 week courses providing they continue to sustain a response.

For second and subsequent courses of PBS-subsidised treatment with adalimumab, etanercept, infliximab or ustekinumab it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Where a response assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to sustain a response to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

(4) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate agent within the same Treatment Cycle without having to requalify with respect to disease severity (i.e. a PASI score of greater than 15), or prior treatment requirements.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

Patients may trial an alternate biological agent at any time, regardless of whether they are receiving therapy with a biological agent at the time of the application or not. However, they cannot swap to a particular agent if they have failed to respond to treatment with that particular agent within the same Cycle.

Patients who commenced treatment with adalimumab prior to 1 June 2009 or ustekinumab prior to 1 March 2010 access these interchangeability arrangements in the same way as patients who have not.
ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the agent being ceased.

(5) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment authority is submitted within a Treatment Cycle and subsequent response will be assessed according to this revised PASI score.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatment applications.

(6) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

Patients who wish to trial a second or subsequent Biological Treatment Cycle, following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment according to the criteria of the relevant restriction and index of disease severity. Patients must have had at least 1 prior treatment, as listed in the criteria, for a minimum of 6 weeks, and must have a PASI assessment conducted preferably whilst still on treatment, but no later than 1 month following cessation of treatment. The PASI assessment must be no older than 1 month at the time of application.

Note
No applications for increased repeats will be authorised.

Note
Special Pricing Arrangements apply.

9305R
ustekinumab 45 mg/0.5 mL injection, 1 x 0.5 mL vial
4601.76 36.90 Stelara JC

Calcineurin inhibitors

CYCLOSPORIN

Authority required
Maintenance therapy, following initiation and stabilisation of treatment with cyclosporin, of patients with organ or tissue transplants. Therapy must remain under the supervision and direction of the transplant unit reviewing the patient. The name of the specialised transplant unit reviewing treatment and the date of the latest review at the specialised transplant unit must be included in the authority application

Authority required
Maintenance therapy, following initiation and stabilisation of treatment with cyclosporin, of patients with severe atopic dermatitis for whom other systemic therapies are ineffective or inappropriate. Therapy must remain under the supervision and direction of a dermatologist, clinical immunologist or specialised unit reviewing the patient. The name of the dermatologist, clinical immunologist or specialised unit reviewing treatment and the date of the latest review must be included in the authority application

Authority required
Maintenance therapy, following initiation and stabilisation of treatment with cyclosporin, of patients with severe psoriasis for whom other systemic therapies are ineffective or inappropriate. Therapy must remain under the supervision and direction of a dermatologist or specialised unit reviewing the patient. The name of the dermatologist or specialised unit reviewing treatment and the date of the latest review must be included in the authority application

Authority required
Maintenance therapy, following initiation and stabilisation of treatment with cyclosporin, of patients with severe active rheumatoid arthritis for whom classical slow-acting anti-rheumatic agents (including methotrexate) are ineffective or inappropriate. Therapy must remain under the supervision and direction of a rheumatologist, clinical immunologist or specialised unit reviewing the patient. The name of the rheumatologist, clinical immunologist or specialised unit reviewing treatment and the date of the latest review must be included in the authority application

Authority required
Management (which includes initiation, stabilisation and review of therapy) by dermatologists or clinical immunologists of patients with severe atopic dermatitis for whom other systemic therapies are ineffective or inappropriate

Authority required
Management (which includes initiation, stabilisation and review of therapy) by dermatologists or clinical immunologists of patients with severe active rheumatoid arthritis for whom classical slow-acting anti-rheumatic agents (including methotrexate) are ineffective or inappropriate

Caution
Careful monitoring of patients is mandatory.

8657P
cyclosporin 10 mg capsule, 60
2 3 .. *94.76 36.90 Neoral 10 NV
## ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

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### TACROLIMUS

**Authority required**

Maintenance therapy, following initiation and stabilisation of treatment with tacrolimus, of patients with organ or tissue transplants. Therapy must remain under the supervision and direction of the transplant unit reviewing the patient. The name of the specialised transplant unit reviewing treatment and the date of the latest review at the specialised transplant unit must be included in the authority application.

**Caution**

Careful monitoring of patients is mandatory.

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### Other immunosuppressants

#### AZATHIOPRINE

**Note**

Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and a medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

<table>
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### METHOTREXATE

**Restricted benefit**
For patients requiring doses greater than 20 mg per week

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<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
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# MUSCULO-SKELETAL SYSTEM

## ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS

### Acetic acid derivatives and related substances

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<th>Code</th>
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**DICLOFENAC**

**Restricted benefit**

- Chronic arthropathies (including osteoarthritis) with an inflammatory component
- Bone pain due to malignant disease

**Restricted benefit**

- Bone pain due to malignant disease

<table>
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**INDOMETHACIN**

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### MUSCULO-SKELETAL SYSTEM

#### INDOMETHACIN

**Restricted benefit**
Chronic arthropathies (including osteoarthritis) with an inflammatory component

**Restricted benefit**
Bone pain due to malignant disease

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#### Oxicams

**MELOXICAM**

**Restricted benefit**
Symptomatic treatment of osteoarthritis

**Restricted benefit**
Symptomatic treatment of rheumatoid arthritis

**Note**
The use of meloxicam for the treatment of the following conditions is not subsidised through the PBS:
(a) acute pain;
(b) soft tissue injury;
(c) arthrosis without an inflammatory component.

**Note**
Pharmaceutical benefits that have the form meloxicam tablet 15 mg and pharmaceutical benefits that have the form meloxicam capsule 15 mg are equivalent for the purposes of substitution.

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#### MELOXICAM

**Restricted benefit**
Symptomatic treatment of osteoarthritis

**Restricted benefit**
Symptomatic treatment of rheumatoid arthritis

**Note**
The use of meloxicam for the treatment of the following conditions is not subsidised through the PBS:
## MUSCULO-SKELETAL SYSTEM

(a) acute pain;  
(b) soft tissue injury;  
(c) arthrosis without an inflammatory component.

**Note**  
Pharmaceutical benefits that have the form meloxicam tablet 7.5 mg and pharmaceutical benefits that have the form meloxicam capsule 7.5 mg are equivalent for the purposes of substitution.

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### PIROXICAM

**Restricted benefit**  
Chronic arthropathies (including osteoarthritis) with an inflammatory component

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# MUSCULO-SKELETAL SYSTEM

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## Propionic acid derivatives

**IBUPROFEN**

**Restricted benefit**

Chronic arthropathies (including osteoarthritis) with an inflammatory component

**Restricted benefit**

Bone pain due to malignant disease

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**KETOROPROFEN**

**Restricted benefit**

Chronic arthropathies (including osteoarthritis) with an inflammatory component

**Restricted benefit**

Bone pain due to malignant disease

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**NAPROXEN**

**Restricted benefit**

Chronic arthropathies (including osteoarthritis) with an inflammatory component

**Restricted benefit**

Bone pain due to malignant disease

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<td>Inza 250 AF</td>
</tr>
<tr>
<td>5176K DP</td>
<td>naproxen 250 mg tablet, 50</td>
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<td>..</td>
<td>..</td>
<td>..</td>
<td>..</td>
<td>Inza 250 AF</td>
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<td>1659H NP</td>
<td>naproxen 500 mg tablet, 50</td>
<td>1</td>
<td>3</td>
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<td>12.94</td>
<td>14.09</td>
<td>Naprosyn MD</td>
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<tr>
<td>5177L DP</td>
<td>naproxen 500 mg tablet, 50</td>
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<td>..</td>
<td>..</td>
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<td>Naprosyn MD</td>
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MUSCULO-SKELETAL SYSTEM

<table>
<thead>
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<th>Name, Restriction, Manner of Administration</th>
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<th>No. of Rpts</th>
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<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>1614Y</td>
<td>naproxen 750 mg tablet: modified release, 28 tablets</td>
<td>1</td>
<td>3</td>
<td>1.22</td>
<td>14.22</td>
<td>14.09</td>
<td>Naprosyn RO MD</td>
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<tr>
<td>5178M</td>
<td>naproxen 750 mg tablet: modified release, 28 tablets</td>
<td>1</td>
<td>..</td>
<td>1.22</td>
<td>13.64</td>
<td>13.57</td>
<td>Proxen SR750 RO MD</td>
</tr>
</tbody>
</table>

**NAPROXEN**

*Authority required (STREAMLINED)*

**4159**

Chronic arthropathies (including osteoarthritis)

**Clinical criteria:**

The condition must have an inflammatory component,

**AND**

Patient must be unable to take a solid dose form of a non-steroidal anti-inflammatory agent.

*Authority required (STREAMLINED)*

**4124**

Bone pain

**Clinical criteria:**

The condition must be due to malignant disease,

**AND**

Patient must be unable to take a solid dose form of a non-steroidal anti-inflammatory agent.

**1658G**

naproxen 125 mg/5 mL oral liquid, 474 mL

1            3            ..          78.51                         36.90               Phebra Naproxen Suspension PL

**NAPROXEN**

**Restricted benefit**

Chronic arthropathies (including osteoarthritis) with an inflammatory component

**Restricted benefit**

Bone pain due to malignant disease

**Note**

Naproxen sodium 550 mg is approximately equivalent to 500 mg of naproxen acid.

**1795L**

naproxen sodium 550 mg tablet, 50

1            3            ..          13.11                         14.26               Crysanal MD

**5186Y**

naproxen sodium 550 mg tablet, 50

1            ..          ..          13.11                         14.26               Anaprox 550 RO MD

**Fenamates**

**MEFENAMIC ACID**

**Restricted benefit**

Dysmenorrhoea

**Restricted benefit**

Menorrhagia

**1824B**

mefenamic acid 250 mg capsule, 50

1            2            ..          18.50                         19.65               Ponstan PF

**Coxibs**

**CELECOXIB**

**Restricted benefit**

Symptomatic treatment of osteoarthritis

**Restricted benefit**

Symptomatic treatment of rheumatoid arthritis

**Note**

The use of celecoxib for the treatment of the following conditions is not subsidised through the PBS:

(a) acute pain;
(b) soft tissue injury;
(c) arthrosis without an inflammatory component.
MUSCULO-SKELETAL SYSTEM

SPECIFIC ANTIRHEUMATIC AGENTS

Quinolines

HYDROXYCHLOROQUINE

Note

Shared Care Model:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

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<thead>
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<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>8439E</td>
<td>celecoxib 100 mg capsule, 60</td>
<td>1</td>
<td>3</td>
<td>..</td>
<td>32.65</td>
<td>33.80</td>
<td>Celebrex PF</td>
</tr>
<tr>
<td>8440F</td>
<td>celecoxib 200 mg capsule, 30</td>
<td>1</td>
<td>3</td>
<td>..</td>
<td>32.65</td>
<td>33.80</td>
<td>Celebrex PF</td>
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</tbody>
</table>

Gold preparations

AURANOFIN

Caution
Regular blood and urine checks are essential.

<table>
<thead>
<tr>
<th>Code</th>
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<th>Brand Name and Manufacturer</th>
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</thead>
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<tr>
<td>2022K</td>
<td>AURANOFIN Capsule 3 mg, 60</td>
<td>1</td>
<td>5</td>
<td>..</td>
<td>779.33</td>
<td>36.90</td>
<td>Ridaura GH</td>
</tr>
</tbody>
</table>

AURANOFIN

Caution
Regular blood and urine checks are essential.

Note
Shared Care Model:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

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<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>1095P</td>
<td>auranofin 3 mg tablet, 60</td>
<td>1</td>
<td>5</td>
<td>..</td>
<td>63.89</td>
<td>36.90</td>
<td>Ridaura GH</td>
</tr>
</tbody>
</table>

AUROTHIOMALATE SODIUM

Caution
Regular blood and urine checks are essential.

Note
Shared Care Model:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

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<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>2016D</td>
<td>aurothiомалate sodium 10 mg/0.5 mL injection, 10 x 0.5 mL ampoules</td>
<td>1</td>
<td>..</td>
<td>..</td>
<td>83.64</td>
<td>36.90</td>
<td>Myocrisin SW</td>
</tr>
<tr>
<td>2017E</td>
<td>aurothiомалate sodium 20 mg/0.5 mL injection, 10 x 0.5 mL ampoules</td>
<td>1</td>
<td>1</td>
<td>..</td>
<td>125.03</td>
<td>36.90</td>
<td>Myocrisin SW</td>
</tr>
<tr>
<td>2018F</td>
<td>aurothiомалate sodium 50 mg/0.5 mL injection, 10 x 0.5 mL ampoules</td>
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<td>1</td>
<td>..</td>
<td>152.81</td>
<td>36.90</td>
<td>Myocrisin SW</td>
</tr>
</tbody>
</table>

Penicillamine and similar agents

PENICILLAMINE

Caution
Regular blood and urine checks are essential.

Note
Shared Care Model:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

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<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>2721F</td>
<td>penicillamine 125 mg tablet, 100</td>
<td>1</td>
<td>1</td>
<td>..</td>
<td>31.97</td>
<td>33.12</td>
<td>D-Penamine AL</td>
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</tbody>
</table>
# MUSCULO-SKELETAL SYSTEM

## MUSCLE RELAXANTS

### MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS

**Other centrally acting agents**

<table>
<thead>
<tr>
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<th>Name, Restriction, Manner of Administration and Form</th>
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<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>2729P</td>
<td>Baclofen 10 mg tablet, 100</td>
<td>1</td>
<td>5</td>
<td>21.78</td>
<td>22.93</td>
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<td>Chem mart Baclofen CH</td>
</tr>
<tr>
<td></td>
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<td>Clofen 10 AF</td>
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<td></td>
<td>GenRx Baclofen GX</td>
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<td>Stelax 10 QA</td>
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<td>Terry White Chemists TW</td>
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<tr>
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<td></td>
<td>Baclofen</td>
</tr>
<tr>
<td>2730Q</td>
<td>Baclofen 25 mg tablet, 100</td>
<td>1</td>
<td>5</td>
<td>39.60</td>
<td>36.90</td>
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<td>Chem mart Baclofen CH</td>
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<td>Baclofen</td>
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<td></td>
<td>Lioresal 10 NV</td>
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</table>

## MUSCLE RELAXANTS, DIRECTLY ACTING AGENTS

### Dantrolene and derivatives

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
<th>Premium Price for Max. Qty $</th>
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<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>1779P</td>
<td>Dantrolene sodium 25 mg capsule, 100</td>
<td>1</td>
<td>2</td>
<td>81.53</td>
<td>36.90</td>
<td></td>
<td>Dantrium PF</td>
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<tr>
<td>1780Q</td>
<td>Dantrolene sodium 50 mg capsule, 100</td>
<td>1</td>
<td>2</td>
<td>82.15</td>
<td>36.90</td>
<td></td>
<td>Dantrium PF</td>
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</tbody>
</table>

## ANTIGOUT PREPARATIONS

### ANTIGOUT PREPARATIONS

**Preparations inhibiting uric acid production**

#### Allopurinol

**Note**
The dose should be adjusted in accordance with renal function.

**Note**
For item codes 2600W and 1557Y, pharmaceutical benefits that have the form tablet 100 mg are equivalent for the purposes of substitution.

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
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<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1557Y</td>
<td>Allopurinol 100 mg tablet, 100</td>
<td>2</td>
<td>2</td>
<td>*12.06</td>
<td>13.21</td>
<td></td>
<td>Progout 100 AF</td>
</tr>
<tr>
<td>2600W</td>
<td>Allopurinol 100 mg tablet, 200</td>
<td>1</td>
<td>2</td>
<td>12.05</td>
<td>13.20</td>
<td></td>
<td>Allopurinol Sandoz Sandoz AF</td>
</tr>
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<td></td>
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<td></td>
<td></td>
<td>Allosig FM</td>
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<td></td>
<td></td>
<td>Chem mart Allopurinol CH</td>
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<td>GenRx Allopurinol GX</td>
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<td>Zylorim QA</td>
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</tbody>
</table>

#### Allopurinol

**Note**
The dose should be adjusted in accordance with renal function.

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<tr>
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<tbody>
<tr>
<td>2604C</td>
<td>Allopurinol 300 mg tablet, 60</td>
<td>1</td>
<td>2</td>
<td>9.88</td>
<td>11.03</td>
<td></td>
<td>Allopurinol Sandoz Sandoz AF</td>
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<td></td>
<td></td>
<td>Allosig FM</td>
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<td></td>
<td></td>
<td></td>
<td>Chem mart Allopurinol CH</td>
</tr>
<tr>
<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>GenRx Allopurinol GX</td>
</tr>
</tbody>
</table>
### Preparations increasing uric acid excretion

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
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<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1940D</td>
<td>PROBENECID probenecid 500 mg tablet, 100</td>
<td>1</td>
<td>5</td>
<td>..</td>
<td>76.03</td>
<td>36.90</td>
<td>Pro-Cid PL</td>
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</tr>
<tr>
<td>3410L</td>
<td>COLCHICINE colchicine 500 microgram tablet, 30</td>
<td>1</td>
<td>5</td>
<td>..</td>
<td>11.34</td>
<td>12.49</td>
<td>Lengout LN</td>
</tr>
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</tbody>
</table>

### Preparations with no effect on uric acid metabolism

#### COLCHICINE colchicine 500 microgram tablet, 30

- Dispensed Price: $3.99
- Dispensed Price: $3.33

### DRUGS AFFECTING BONE STRUCTURE AND MINERALIZATION

#### Bisphosphonates

**ALENDRONATE**  
**Authority required (STREAMLINED)**

- **3256** Symptomatic Paget disease of bone
- **8090T** alendronate 40 mg tablet, 30

**Note**  
Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.
### MUSCULO-SKELETAL SYSTEM

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<tr>
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</thead>
<tbody>
<tr>
<td></td>
<td>AND</td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.</td>
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<tr>
<td></td>
<td>The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated.</td>
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</tr>
<tr>
<td></td>
<td>A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.</td>
<td></td>
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</tr>
<tr>
<td></td>
<td><strong>Note</strong> Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride, strontium ranelate and zoledronic acid.</td>
<td></td>
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</tr>
</tbody>
</table>

#### CLODRONATE

**Restricted benefit**

Maintenance treatment of hypercalcaemia of malignancy refractory to anti-neoplastic therapy

**Restricted benefit**

Multiple myeloma

**Restricted benefit**

Bone metastases from breast cancer

**Note**

Continuing Therapy Only:

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<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>8132B</td>
<td>clodronate sodium 400 mg capsule, 100</td>
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<td>2</td>
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<td>334.42</td>
<td>36.90</td>
<td>Bonefos BN</td>
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<tr>
<td>8265B</td>
<td>clodronate sodium 800 mg tablet, 60</td>
<td>1</td>
<td>2</td>
<td></td>
<td>391.78</td>
<td>36.90</td>
<td>Bonefos 800 mg BN</td>
</tr>
</tbody>
</table>

#### IBANDRONIC ACID

**Restricted benefit**

Bone metastases from breast cancer

**Note**

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

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<td>342.68</td>
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#### PAMIDRONATE DISODIUM

**Authority required (STREAMLINED)**

4422

Symptomatic Paget disease of bone

**Note**

Continuing Therapy Only:

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MUSCULO-SKELETAL SYSTEM

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<td>pamidronate disodium 60 mg/10 mL injection, 1 x 10 mL vial</td>
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PAMIDRONATE DISODIUM

**Authority required (STREAMLINED)**

4420

Symptomatic Paget disease of bone

**Note**

Pharmaceutical benefits that have the form disodium pamidronate powder for I.V. infusion 30 mg (after reconstitution) and pharmaceutical benefits that have the form disodium pamidronate concentrated injection 30 mg are equivalent for the purposes of substitution.

**Note**

**Continuing Therapy Only:**

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8209C

<table>
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RISEDRONATE

**Authority required (STREAMLINED)**

4122

Corticosteroid-induced osteoporosis

**Clinical criteria:**

Patient must currently be on long-term (at least 3 months), high-dose (at least 7.5 mg per day prednisolone or equivalent) corticosteroid therapy, AND

Patient must have a Bone Mineral Density (BMD) T-score of -1.5 or less, AND

Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The duration and dose of corticosteroid therapy together with the date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient’s medical records when treatment is initiated.

**Authority required (STREAMLINED)**

4133

Osteoporosis

**Clinical criteria:**

Patient must have a Bone Mineral Density (BMD) T-score of -2.5 or less, AND

Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient’s medical records when treatment is initiated.

4473

Established osteoporosis

**Clinical criteria:**

Patient must have fracture due to minimal trauma, AND

Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient’s medical records when treatment is initiated.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral
MUSCULO-SKELETAL SYSTEM

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RISEDRONATE

**Authority required (STREAMLINED)**

3256

Symptomatic Paget disease of bone

Note

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

8482K

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TILUDRONATE

**Authority required (STREAMLINED)**

3256

Symptomatic Paget disease of bone

Note

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

8267D

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ZOLEDRONIC ACID

**Authority required (STREAMLINED)**

4100

Corticosteroid-induced osteoporosis

Clinical criteria:

Patient must currently be on long-term (at least 3 months), high-dose (at least 7.5 mg per day prednisolone or equivalent) corticosteroid therapy, AND

Patient must have a Bone Mineral Density (BMD) T-score of -1.5 or less, AND

Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition, AND

Patient must not receive more than one PBS-subsidised treatment per year.

The duration and dose of corticosteroid therapy together with the date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient’s medical records when treatment is initiated.

**Authority required (STREAMLINED)**

4149

Note

Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride, strontium ranelate and zoledronic acid.
MUSCULO-SKELETAL SYSTEM

Osteoporosis

Clinical criteria:
Patient must have a Bone Mineral Density (BMD) T-score of -3.0 or less,
AND
Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition,
AND
Patient must not receive more than one PBS-subsidised treatment per year.

Population criteria:
Patient must be aged 70 years or older.
The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient’s medical records when treatment is initiated.

Authority required (STREAMLINED)
4157
Established osteoporosis

Clinical criteria:
Patient must have fracture due to minimal trauma,
AND
Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition,
AND
Patient must not receive more than one PBS-subsidised treatment per year.

The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient’s medical records when treatment is initiated.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

Note
Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride, strontium ranelate and zoledronic acid.

9288W zoledronic acid 5 mg/100 mL injection, 1 x 100 mL vial

ZOLEDRONIC ACID

Authority required
Symptomatic Paget disease of bone.
Only 1 treatment each year per patient will be PBS-subsidised

9350D zoledronic acid 5 mg/100 mL injection, 1 x 100 mL vial

Bisphosphonates, combinations

ALENDRONATE + COLECALCIFEROL

Authority required (STREAMLINED)
4122
Corticosteroid-induced osteoporosis

Clinical criteria:
Patient must currently be on long-term (at least 3 months), high-dose (at least 7.5 mg per day prednisolone or equivalent) corticosteroid therapy,
AND
Patient must have a Bone Mineral Density (BMD) T-score of -1.5 or less,
AND
Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.
The duration and dose of corticosteroid therapy together with the date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient’s medical records when treatment is initiated.

Authority required (STREAMLINED)
4133
Osteoporosis
MUSCULO-SKELETAL SYSTEM

Clinical criteria:
Patient must have a Bone Mineral Density (BMD) T-score of -2.5 or less,
AND
Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

Population criteria:
Patient must be aged 70 years or older.
The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient’s medical records when treatment is initiated.

Authority required (STREAMLINED)
4123
Established osteoporosis
Clinical criteria:
Patient must have fracture due to minimal trauma,
AND
Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient’s medical records when treatment is initiated.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

Note
Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride, strontium ranelate and zoledronic acid.

9183H
alendronate 70 mg + colecalciferol 140 microgram tablet, 4
1 5 .. 45.51 36.90 a
Alendronate plus D3-
RZ
DRLA
GN
AF
MK

ALENDRONATE + COLECALCIFEROL
Authority required (STREAMLINED)
4070
Corticosteroid-induced osteoporosis
Clinical criteria:
Patient must currently be on long-term (at least 3 months), high-dose (at least 7.5 mg per day prednisolone or equivalent) corticosteroid therapy,
AND
Patient must have a Bone Mineral Density (BMD) T-score of -1.5 or less,
AND
Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.
The duration and dose of corticosteroid therapy together with the date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient’s medical records when treatment is initiated.

Authority required (STREAMLINED)
4110
Osteoporosis
Clinical criteria:
Patient must have a Bone Mineral Density (BMD) T-score of -2.5 or less,
AND
Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

Population criteria:
Patient must be aged 70 years or older.
The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient’s medical records when treatment is initiated.

Authority required (STREAMLINED)
4087
Established osteoporosis

Clinical criteria:

Patient must have fracture due to minimal trauma,

AND

Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient’s medical records when treatment is initiated.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

Note

Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride, strontium ranelate and zoledronic acid.

Note

Fosamax Plus provides a supplemental intake of vitamin D. The amount of colecalciferol present in Fosamax Plus is not sufficient to use as the sole treatment for correction of vitamin D deficiency.

9012H

alendronate 70 mg + colecalciferol 70 microgram tablet, 4

Max. Qty (Packs)  No. of Rpts  Premium $  Dispensed Price for Max. Qty $  Maximum Recordable Value for Safety Net $  Brand Name and Manufacturer

45.51  36.90  Fosamax Plus  MK


Authority required (STREAMLINED)

4122

Corticosteroid-induced osteoporosis

Clinical criteria:

Patient must currently be on long-term (at least 3 months), high-dose (at least 7.5 mg per day prednisolone or equivalent) corticosteroid therapy,

AND

Patient must have a Bone Mineral Density (BMD) T-score of -1.5 or less,

AND

Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The duration and dose of corticosteroid therapy together with the date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient’s medical records when treatment is initiated.

Authority required (STREAMLINED)

4133

Osteoporosis

Clinical criteria:

Patient must have a Bone Mineral Density (BMD) T-score of -2.5 or less,

AND

Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

Population criteria:

Patient must be aged 70 years or older.

The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient’s medical records when treatment is initiated.

Authority required (STREAMLINED)

4123

Established osteoporosis

Clinical criteria:

Patient must have fracture due to minimal trauma,

AND

Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient’s medical records when treatment is initiated.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.
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</table>

**Note**

Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride, strontium ranelate and zoledronic acid.

### RISEDRONATE (6) CALCIUM CARBONATE

**Authority required [STREAMLINED]**

#### 4122
Corticosteroid-induced osteoporosis

**Clinical criteria:**

- Patient must currently be on long-term (at least 3 months), high-dose (at least 7.5 mg per day prednisolone or equivalent) corticosteroid therapy, AND
- Patient must have a Bone Mineral Density (BMD) T-score of -1.5 or less, AND
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The duration and dose of corticosteroid therapy together with the date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient’s medical records when treatment is initiated.

**Authority required [STREAMLINED]**

#### 4133
Osteoporosis

**Clinical criteria:**

- Patient must have a Bone Mineral Density (BMD) T-score of -2.5 or less, AND
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

**Population criteria:**

- Patient must be aged 70 years or older.

The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient’s medical records when treatment is initiated.

**Authority required [STREAMLINED]**

#### 4123
Established osteoporosis

**Clinical criteria:**

- Patient must have fracture due to minimal trauma, AND
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient’s medical records when treatment is initiated.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

**Note**

Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride, strontium ranelate and zoledronic acid.
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<td>Osteoporosis</td>
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<td>‡1</td>
<td>5</td>
<td>...</td>
<td>45.73</td>
<td>36.90</td>
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Other drugs affecting bone structure and mineralization

CALCITRIOL Authority required (STREAMLINED) 1165 Hypocalcaemia due to renal disease Authority required (STREAMLINED)
MUSCULO-SKELETAL SYSTEM

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**DENOSUMAB**

*Authority required (STREAMLINED)*

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<td>4504</td>
<td>Giant cell tumour of bone</td>
<td>1</td>
<td>5</td>
<td>..</td>
<td>532.31</td>
<td>36.90</td>
<td>Xgeva AN</td>
</tr>
</tbody>
</table>

**Note**

Denosumab is not PBS-subsidised for use in patients who have undergone curative surgical resection.

**Note**

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

<table>
<thead>
<tr>
<th>Code</th>
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<td>4158</td>
<td>Bone metastases</td>
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<td>532.31</td>
<td>36.90</td>
<td>Xgeva AN</td>
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</table>

**DENOSUMAB**

*Authority required (STREAMLINED)*

<table>
<thead>
<tr>
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<td>..</td>
<td>532.31</td>
<td>36.90</td>
<td>Xgeva AN</td>
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**Note**

Continuing Therapy Only:
MUSCULO-SKELETAL SYSTEM

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<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>5110Y NP</td>
<td>denosumab 120 mg/1.7 mL injection, 1 x 1.7 mL vial</td>
<td>1</td>
<td>5</td>
<td>..</td>
<td>532.31</td>
<td>36.90</td>
<td>Xgeva AN</td>
</tr>
</tbody>
</table>

DENOSUMAB

Authority required (STREAMLINED)

4314

Osteoporosis

Clinical criteria:

Patient must have a Bone Mineral Density (BMD) T-score of -2.5 or less,
AND

Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

Population criteria:

Patient must be aged 70 years or older.

The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

Authority required (STREAMLINED)

4347

Established osteoporosis

Clinical criteria:

Patient must have fracture due to minimal trauma,
AND

Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

Note

Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride, strontium ranelate and zoledronic acid.

Note

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

5457F NP | denosumab 60 mg/mL injection, 1 x 1 mL syringe | 1                | ..          | ..        | 296.00                         | 36.90                              | Prolia AN                   |

RALOXIFENE

Authority required (STREAMLINED)

4071

Established post-menopausal osteoporosis

Clinical criteria:

Patient must have fracture due to minimal trauma,
AND

Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

Note

Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride,
<table>
<thead>
<tr>
<th>Code</th>
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<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>8363E NP</td>
<td>strontium ranelate and zoledronic acid. raloxifene hydrochloride 60 mg tablet, 28 g sachets</td>
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<td>5</td>
<td>..</td>
<td>58.21</td>
<td>36.90</td>
<td>Evista LY</td>
</tr>
</tbody>
</table>

**STRONTIUM**

*Authority required (STREAMLINED)*

4123

*Established osteoporosis*

*Clinical criteria:*

Patient must have fracture due to minimal trauma,

AND

Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient’s medical records when treatment is initiated.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

**Note**

Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride, strontium ranelate and zoledronic acid.

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<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>3036T NP</td>
<td>strontium ranelate 2 g granules, 28 x 2 g sachets</td>
<td>1</td>
<td>5</td>
<td>..</td>
<td>52.00</td>
<td>36.90</td>
<td>Protos 2 g SE</td>
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</tbody>
</table>

**TERIPARATIDE**

*Authority required*

Severe established osteoporosis

*Treatment Phase: Initial treatment*

*Clinical criteria:*

Patient must be at very high risk of fracture,

AND

Patient must have a bone mineral density (BMD) T-score of -3.0 or less,

AND

Patient must have had 2 or more fractures due to minimal trauma,

AND

Patient must have experienced at least 1 symptomatic new fracture after at least 12 months continuous therapy with an anti-resorptive agent at adequate doses,

AND

The treatment must be the sole PBS-subsidised agent,

AND

The treatment must not exceed a lifetime maximum of 18 months therapy.

*Treatment criteria:*

Must be treated by a specialist; OR

Must be treated by a consultant physician.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

If treatment with anti-resorptive therapy is contraindicated according to the relevant TGA-approved Product Information, details of the contraindication must be documented in the patient’s medical record at the time treatment with teriparatide is initiated.

If an intolerance of a severity necessitating permanent treatment withdrawal develops during the relevant period of use of one anti-resorptive agent, alternate anti-resorptive agents must be trialled so that the patient achieves the minimum requirement of 12 months continuous therapy. Details must be documented in the patient’s medical record at the time treatment with teriparatide is initiated.

Anti-resorptive therapies for osteoporosis and their adequate doses which will be accepted for the purposes of administering this restriction are alendronate sodium 10 mg per day or 70 mg once weekly, risedronate sodium 5 mg per day or 35 mg once weekly or 150 mg once monthly, raloxifene hydrochloride 60 mg per day (women only), denosumab 60 mg once every 6 months, strontium ranelate 2 g per day and zoledronic acid 5 mg per annum.

Details of prior anti-resorptive therapy, fracture history including the date(s), site(s), the symptoms associated with the fracture(s) which developed...
after at least 12 months continuous anti-resorptive therapy and the score of the qualifying BMD measurement must be provided at the time of application.

**Note**
Details of accepted toxicities including severity can be found on the Department of Human Services website at www.humanservices.gov.au.

**Note**
No increase in the maximum quantity or number of units may be authorised.

**Note**
No increase in the maximum number of repeats may be authorised.

**Note**
Special Pricing Arrangements apply.

**Authority required**
Severe established osteoporosis
Treatment Phase: Continuing treatment

**Clinical criteria:**
Patient must have previously been issued with an authority prescription for this drug,

AND

The treatment must not exceed a lifetime maximum of 18 months therapy.

**Note**
Up to a maximum of 18 pens will be reimbursed through the PBS.

**Note**
No increase in the maximum quantity or number of units may be authorised.

**Note**
No increase in the maximum number of repeats may be authorised.

**Note**
Special Pricing Arrangements apply.

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<td>9411H</td>
<td>teriparatide 20 microgram/dose injection, 1 x 2.4 mL cartridge</td>
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<td>438.71</td>
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### ANALGESICS

#### OPIOIDS

*Natural opium alkaloids*

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<td>CODEINE codeine phosphate 30 mg tablet, 20</td>
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<td>..</td>
<td>17.21</td>
<td>18.36</td>
<td>Fawns and McAllan Proprietary Limited FM</td>
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<tr>
<td>NP</td>
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<td></td>
<td></td>
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<td></td>
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<tr>
<td>5063L</td>
<td>CODEINE Note Prescribing of drugs of addiction by dentists is not permitted in some States/Territories.</td>
<td>1</td>
<td>..</td>
<td>17.21</td>
<td>18.36</td>
<td>Fawns and McAllan Proprietary Limited FM</td>
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<tr>
<td>DP</td>
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<td></td>
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<tr>
<td>5132D</td>
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<td>64.04</td>
<td>36.90</td>
<td>Dilaudid MF</td>
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<td>5117H</td>
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<td>30.37</td>
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<tr>
<td>8424J</td>
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<td>36.90</td>
<td>Dilaudid MF</td>
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<tr>
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<td>20.19</td>
<td>21.34</td>
<td>Dilaudid MF</td>
</tr>
<tr>
<td>NP</td>
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<td>30.37</td>
<td>31.52</td>
<td>Dilaudid MF</td>
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<tr>
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<td></td>
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<tr>
<td>8421F</td>
<td>HYDROMORPHONE hydromorphone hydrochloride 10 mg/mL oral liquid, 473 mL</td>
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<td>..</td>
<td>29.31</td>
<td>30.46</td>
<td>Dilaudid-HP MF</td>
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</table>

**Note**
Prescribing of drugs of addiction by dentists is not permitted in some States/Territories.

**Caution**
The risk of drug dependence is high.

**Authorities for increased maximum quantities and/or repeats will be granted only for:**

(i) severe disabling pain associated with proven malignant neoplasia; or

(ii) chronic severe disabling pain not responding to non-narcotic analgesics where the total duration of narcotic analgesic treatment is less than 12 months; or

(iii) first application for treatment beyond 12 months of chronic severe disabling pain not responding to non-narcotic analgesics where the patient's pain management has been reviewed through consultation by the patient with another medical practitioner, and the clinical need for continuing narcotic analgesic treatment has been confirmed. The date of the consultation must be no more than 3 months prior to the application for a PBS authority. The full name of the medical practitioner consulted and the date of consultation are to be provided at the time of application; or

(iv) subsequent application for treatment of chronic severe disabling pain not responding to non-narcotic analgesics where a PBS authority prescription for treatment beyond 12 months has previously been issued for this patient.
HYDROMORPHONE

Restricted benefit

Chronic severe disabling pain not responding to non-narcotic analgesics

Caution

The risk of drug dependence is high.

Note

Authorities for increased maximum quantities and/or repeats will be granted only for:

(i) chronic severe disabling pain associated with proven malignant neoplasia; or

(ii) chronic severe disabling pain not responding to non-narcotic analgesics where the total duration of narcotic analgesic treatment is less than 12 months; or

(iii) first application for treatment beyond 12 months of chronic severe disabling pain not responding to non-narcotic analgesics where the patient’s pain management has been reviewed through consultation by the patient with another medical practitioner, and the clinical need for continuing narcotic analgesic treatment has been confirmed. The date of the consultation must be no more than 3 months prior to the application for a PBS authority. The full name of the medical practitioner consulted and the date of consultation are to be provided at the time of application; or

(iv) subsequent application for treatment of chronic severe disabling pain not responding to non-narcotic analgesics where a PBS authority prescription for treatment beyond 12 months has previously been issued for this patient.

MORPHINE

Restricted benefit

Chronic severe disabling pain not responding to non-narcotic analgesics

Caution

The risk of drug dependence is high.

Note

 Authorities for increased maximum quantities and/or repeats will be granted only for:

(i) chronic severe disabling pain associated with proven malignant neoplasia; or

(ii) chronic severe disabling pain not responding to non-narcotic analgesics where the total duration of narcotic analgesic treatment is less than 12 months; or

(iii) first application for treatment beyond 12 months of chronic severe disabling pain not responding to non-narcotic analgesics where the patient’s pain management has been reviewed through consultation by the patient with another medical practitioner, and the clinical need for continuing narcotic analgesic treatment has been confirmed. The date of the consultation must be no more than 3 months prior to the application for a PBS authority. The full name of the medical practitioner consulted and the date of consultation are to be provided at the time of application; or

(iv) subsequent application for treatment of chronic severe disabling pain not responding to non-narcotic analgesics where a PBS authority prescription for treatment beyond 12 months has previously been issued for this patient.
### NERVOUS SYSTEM

#### Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Dispensed Price for Max. Qty $ | Maximum Recordable Value for Safety Net $ | Brand Name and Manufacturer  
--- | --- | --- | --- | --- | --- | --- | ---  
8305D | morphine Sachet containing controlled release granules for oral suspension, 60 mg per sachet, 28 | 1 | .. | .. | 70.21 | 36.90 | MS Contin Suspension 60 mg  
1653B | morphine sulfate 10 mg tablet: modified release, 28 tablets | 1 | .. | .. | 20.38 | 21.53 | a APOTEX-MORPHINE MR TX  
8306E | morphine sulfate 100 mg granules: modified release, 28 sachets | 1 | .. | .. | 86.71 | 36.90 | a MS Contin Suspension 100 mg  
1656E | morphine sulfate 100 mg tablet: modified release, 28 tablets | 1 | .. | .. | 72.85 | 36.90 | a APOTEX-MORPHINE MR TX  
8494C | morphine sulfate 120 mg capsule: modified release, 14 capsules | 1 | .. | .. | 54.81 | 36.90 |  
8498T | morphine sulfate 15 mg tablet: modified release, 28 tablets | 1 | .. | .. | 24.57 | 25.72 | MS Contin  
8490W | morphine sulfate 20 mg granules: modified release, 28 sachets | 1 | .. | .. | 60.63 | 36.90 | MS Contin Suspension 20 mg  
8491X | morphine sulfate 30 mg capsule: modified release, 14 capsules | 1 | .. | .. | 24.56 | 25.71 | MS Mono  
1654C | morphine sulfate 30 mg tablet: modified release, 28 tablets | 1 | .. | .. | 36.23 | 36.90 | a APOTEX-MORPHINE MR TX  
8035X | morphine sulfate 5 mg tablet: modified release, 28 tablets | 1 | .. | .. | 17.95 | 19.10 | a MS Contin  
8492Y | morphine sulfate 60 mg capsule: modified release, 14 capsules | 1 | .. | .. | 36.21 | 36.90 | MS Mono  
1655D | morphine sulfate 60 mg tablet: modified release, 28 tablets | 1 | .. | .. | 54.82 | 36.90 | a APOTEX-MORPHINE MR TX  
8493B | morphine sulfate 90 mg capsule: modified release, 14 capsules | 1 | .. | .. | 41.76 | 36.90 |  

**MORPHINE**  
**Restricted benefit**  
Severe disabling pain not responding to non-narcotic analgesics  

**Caution**  
The risk of drug dependence is high.  

**Note**  
Authorities for increased maximum quantities and/or repeats will be granted only for:  
(i) severe disabling pain associated with proven malignant neoplasia; or  
(ii) chronic severe disabling pain not responding to non-narcotic analgesics where the total duration of narcotic analgesic treatment is less than 12 months; or  
(iii) first application for treatment beyond 12 months of chronic severe disabling pain not responding to non-narcotic analgesics where the patient’s pain management has been reviewed through consultation by the patient with another medical practitioner, and the clinical need for continuing narcotic analgesic treatment has been confirmed. The date of the consultation must be no more than 3 months prior to the application for a PBS authority. The full name of the medical practitioner consulted and the date of consultation are to be provided at the time of application; or  
(iv) subsequent application for treatment of chronic severe disabling pain not responding to non-narcotic analgesics where a PBS authority prescription for treatment beyond 12 months has previously been issued for this patient.  

2124T | morphine hydrochloride 10 mg/mL oral liquid, 200 mL | 1 | .. | .. | 27.20 | 28.35 | Ordine 10  
2122Q | morphine hydrochloride 2 mg/mL oral liquid, 200 mL | 1 | .. | .. | 20.67 | 21.82 | Ordine 2  
2123R | morphine hydrochloride 5 mg/mL oral liquid, 200 mL | 1 | .. | .. | 23.07 | 24.22 | Ordine 5  
1646P | morphine sulfate 30 mg tablet, 20 | 1 | .. | .. | 14.37 | 15.52 | Anamorph  

**MORPHINE**  
**Restricted benefit**  
Severe disabling pain not responding to non-narcotic analgesics  

**Caution**
NERVOUS SYSTEM

<table>
<thead>
<tr>
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<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
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<td>..</td>
<td>..</td>
<td>27.20</td>
<td>28.35</td>
<td>Ordine 10</td>
</tr>
<tr>
<td>5237P</td>
<td>morphone hydrochloride 2 mg/mL oral liquid, 200 mL</td>
<td>1</td>
<td>..</td>
<td>..</td>
<td>20.67</td>
<td>21.82</td>
<td>Ordine 2</td>
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<tr>
<td>5238Q</td>
<td>morphone hydrochloride 5 mg/mL oral liquid, 200 mL</td>
<td>1</td>
<td>..</td>
<td>..</td>
<td>23.07</td>
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<td>Ordine 5</td>
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<tr>
<td>5163R</td>
<td>morphone sulfate 30 mg tablet, 20</td>
<td>1</td>
<td>..</td>
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<td>14.37</td>
<td>15.52</td>
<td>Anamorph FM</td>
</tr>
</tbody>
</table>

MORPHINE

Restricted benefit
Severe disabling pain due to cancer not responding to non-narcotic analgesics

Caution
The risk of drug dependence is high.

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
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<td>8670H</td>
<td>morphone sulfate 20 mg tablet, 20</td>
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<td>16.75</td>
<td>Sevredol MF</td>
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MORPHINE

Caution
The risk of drug dependence is high.

<table>
<thead>
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<th>Max. Qty (Packs)</th>
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<td>20.58</td>
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<td>39.62</td>
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MORPHINE

Caution
The risk of drug dependence is high.

Note
Prescribing of drugs of addiction by dentists is not permitted in some States/Territories.

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<th>Code</th>
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<td>20.58</td>
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</table>

MORPHINE

Authority required
Chronic severe disabling pain due to cancer

Caution
The risk of drug dependence is high.

Note
Prescribing of drugs of addiction by dentists is not permitted in some States/Territories.

<table>
<thead>
<tr>
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<th>Name, Restriction, Manner of Administration and Form</th>
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</thead>
<tbody>
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<td>..</td>
<td>164.09</td>
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<td>MS Contin Suspension 200 mg MF</td>
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<tr>
<td>8453X</td>
<td>morphone sulfate 200 mg tablet: modified release, 28 tablets</td>
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<td>..</td>
<td>..</td>
<td>122.20</td>
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<td>MS Contin MF</td>
</tr>
</tbody>
</table>

OXYCODONE

Restricted benefit
Severe disabling pain not responding to non-narcotic analgesics

Caution
The risk of drug dependence is high.

Note
Authorities for increased maximum quantities and/or repeats will be granted only for:
(i) severe disabling pain associated with proven malignant neoplasia; or
OXYCODONE

Restricted benefit

Severe disabling pain not responding to non-narcotic analgesics

Caution
The risk of drug dependence is high.

Note
Prescribing of drugs of addiction by dentists is not permitted in some States/Territories.

OXYCODONE

Restricted benefit

Chronic severe disabling pain not responding to non-narcotic analgesics

Caution
The risk of drug dependence is high.

Note
Authorities for increased maximum quantities and/or repeats will be granted only for:
(i) chronic severe disabling pain associated with proven malignant neoplasia; or
(ii) first application for treatment beyond 12 months of chronic severe disabling pain not responding to non-narcotic analgesics where the total duration of narcotic analgesic treatment is less than 12 months; or
(iii) first application for treatment beyond 12 months of chronic severe disabling pain not responding to non-narcotic analgesics where the patient’s pain management has been reviewed through consultation by the patient with another medical practitioner, and the clinical need for continuing narcotic analgesic treatment has been confirmed. The date of the consultation must be no more than 3 months prior to the application for a PBS authority. The full name of the medical practitioner consulted and the date of consultation are to be provided at the time of application; or
(iv) subsequent application for treatment of chronic severe disabling pain not responding to non-narcotic analgesics where a PBS authority prescription for treatment beyond 12 months has previously been issued for this patient.
NERVOUS SYSTEM

<table>
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</table>

**OXYCODONE + NALOXONE**

**Restricted benefit**

Chronic severe disabling pain not responding to non-narcotic analgesics

**Caution**
The risk of drug dependence is high.

**Note**
Authorities for increased maximum quantities and/or repeats will be granted only for:

(i) chronic severe disabling pain associated with proven malignant neoplasia; or

(ii) chronic severe disabling pain not responding to non-narcotic analgesics where the total duration of narcotic analgesic treatment is less than 12 months; or

(iii) first application for treatment beyond 12 months of chronic severe disabling pain not responding to non-narcotic analgesics where the patient’s pain management has been reviewed through consultation by the patient with another medical practitioner, and the clinical need for continuing narcotic analgesic treatment has been confirmed. The date of the consultation must be no more than 3 months prior to the application for a PBS authority. The full name of the medical practitioner consulted and the date of consultation are to be provided at the time of application; or

(iv) subsequent application for treatment of chronic severe disabling pain not responding to non-narcotic analgesics where a PBS authority prescription for treatment beyond 12 months has previously been issued for this patient.

**Note**
Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**PARACETAMOL + CODEINE**

**Note**
Authorities for increased maximum quantities and/or repeats will not be granted except as detailed under the ‘Authority required’ listing of codeine phosphate with paracetamol below.

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**PARACETAMOL + CODEINE**

**Note**

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**PARACETAMOL + CODEINE**

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NERVOUS SYSTEM

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**Phenylpiperidine derivatives**

**FENTANYL**

**Restricted benefit**

Chronic severe disabling pain not responding to non-narcotic analgesics

**Caution**

The risk of drug dependence is high.

**Note**

Authorities for increased maximum quantities and/or repeats will be granted only for:

(i) chronic severe disabling pain associated with proven malignant neoplasmia; or

(ii) chronic severe disabling pain not responding to non-narcotic analgesics where the total duration of narcotic analgesic treatment is less than 12 months; or

(iii) first application for treatment beyond 12 months of chronic severe disabling pain not responding to non-narcotic analgesics where the patient's pain management has been reviewed through consultation by the patient with another medical practitioner, and the clinical need for continuing narcotic analgesic treatment has been confirmed. The date of the consultation must be no more than 3 months prior to the application for a PBS authority. The full name of the medical practitioner consulted and the date of consultation are to be provided at the time of application; or

(iv) subsequent application for treatment of chronic severe disabling pain not responding to non-narcotic analgesics where a PBS authority prescription for treatment beyond 12 months has previously been issued for this patient.

**Note**

Fentanyl transdermal patches are not recommended in opioid naive patients with non-cancer pain, because of a high incidence of adverse events in these patients. Patients with cancer pain may be initiated on the lowest strength patch (12 micrograms per hour).

Pharmaceutical benefits that have the forms fentanyl transdermal patch 16.5 mg, fentanyl transdermal patch 10.20 mg and fentanyl transdermal patch 16.8 mg (all releasing approximately 100 micrograms per hour) are equivalent for the purposes of substitution.

<table>
<thead>
<tr>
<th>Code</th>
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<td>5280X</td>
<td>fentanyl 100 microgram/hour patch, 5</td>
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<td>..</td>
<td>84.81</td>
<td>36.90</td>
<td>a Denpax</td>
<td>AF</td>
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<tr>
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<td>36.90</td>
<td>a Dutran 100</td>
<td>GN</td>
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<td></td>
<td>Fentanyl Sandoz SZ</td>
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</tbody>
</table>

**FENTANYL**

**Restricted benefit**

Chronic severe disabling pain not responding to non-narcotic analgesics

**Caution**

The risk of drug dependence is high.

**Note**

Authorities for increased maximum quantities and/or repeats will be granted only for:

(i) chronic severe disabling pain associated with proven malignant neoplasmia; or

(ii) chronic severe disabling pain not responding to non-narcotic analgesics where the total duration of narcotic analgesic treatment is less than 12 months; or

(iii) first application for treatment beyond 12 months of chronic severe disabling pain not responding to non-narcotic analgesics where the patient's pain management has been reviewed through consultation by the patient with another medical practitioner, and the clinical need for
continuing narcotic analgesic treatment has been confirmed. The date of the consultation must be no more than 3 months prior to the application for a PBS authority. The full name of the medical practitioner consulted and the date of consultation are to be provided at the time of application; or

(iv) subsequent application for treatment of chronic severe disabling pain not responding to non-narcotic analgesics where a PBS authority prescription for treatment beyond 12 months has previously been issued for this patient.

Note
Fentanyl transdermal patches are not recommended in opioid naive patients with non-cancer pain, because of a high incidence of adverse events in these patients. Patients with cancer pain may be initiated on the lowest strength patch (12 micrograms per hour).

Pharmaceutical benefits that have the forms fentanyl transdermal patch 2.063 mg, fentanyl transdermal patch 1.28 mg and fentanyl transdermal patch 2.1 mg (all releasing approximately 12 micrograms per hour) are equivalent for the purposes of substitution.

5265D
fentanyl 12 microgram/hour patch, 5
1 .. .. 29.30 30.45 a Denpax AF
5437E
fentanyl 12 microgram/hour patch, 5
1 .. .. 29.30 30.45 a Dutran 12 GN
8878G
fentanyl 12 microgram/hour patch, 5
1 .. .. 29.30 30.45 a Fenpatch 12 ZP

Fentanyl Sandoz SZ

FENTANYL
Restricted benefit
Chronic severe disabling pain not responding to non-narcotic analgesics

Caution
The risk of drug dependence is high.

Note
Authorities for increased maximum quantities and/or repeats will be granted only for:

(i) chronic severe disabling pain associated with proven malignant neoplasia; or
(ii) chronic severe disabling pain not responding to non-narcotic analgesics where the total duration of narcotic analgesic treatment is less than 12 months; or
(iii) first application for treatment beyond 12 months of chronic severe disabling pain not responding to non-narcotic analgesics where the patient’s pain management has been reviewed through consultation by the patient with another medical practitioner, and the clinical need for continuing narcotic analgesic treatment has been confirmed. The date of the consultation must be no more than 3 months prior to the application for a PBS authority. The full name of the medical practitioner consulted and the date of consultation are to be provided at the time of application; or
(iv) subsequent application for treatment of chronic severe disabling pain not responding to non-narcotic analgesics where a PBS authority prescription for treatment beyond 12 months has previously been issued for this patient.

Note
Fentanyl transdermal patches are not recommended in opioid naive patients with non-cancer pain, because of a high incidence of adverse events in these patients. Patients with cancer pain may be initiated on the lowest strength patch (12 micrograms per hour).

Pharmaceutical benefits that have the forms fentanyl transdermal patch 4.125 mg, fentanyl transdermal patch 2.55 mg and fentanyl transdermal patch 4.2 mg (all releasing approximately 25 micrograms per hour) are equivalent for the purposes of substitution.

5277R
fentanyl 25 microgram/hour patch, 5
1 .. .. 34.67 35.82 a Denpax AF
5438F
fentanyl 25 microgram/hour patch, 5
1 .. .. 34.67 35.82 a Dutran 25 GN
8891Y
fentanyl 25 microgram/hour patch, 5
1 .. .. 34.67 35.82 a Fenpatch 25 ZP

Fentanyl Sandoz SZ
continuing narcotic analgesic treatment has been confirmed. The date of the consultation must be no more than 3 months prior to the application for a PBS authority. The full name of the medical practitioner consulted and the date of consultation are to be provided at the time of application; or

(iv) subsequent application for treatment of chronic severe disabling pain not responding to non-narcotic analgesics where a PBS authority prescription for treatment beyond 12 months has previously been issued for this patient.

Note
Fentanyl transdermal patches are not recommended in opioid naive patients with non-cancer pain, because of a high incidence of adverse events in these patients. Patients with cancer pain may be initiated on the lowest strength patch (12 micrograms per hour).

Pharmaceutical benefits that have the forms fentanyl transdermal patch 8.25 mg, fentanyl transdermal patch 5.10 mg and fentanyl transdermal patch 8.4 mg (all releasing approximately 50 micrograms per hour) are equivalent for the purposes of substitution.

FENTANYL
Restricted benefit
Chronic severe disabling pain not responding to non-narcotic analgesics

Caution
The risk of drug dependence is high.

Note
Authorities for increased maximum quantities and/or repeats will be granted only for:

(i) chronic severe disabling pain associated with proven malignant neoplasia; or

(ii) chronic severe disabling pain not responding to non-narcotic analgesics where the total duration of narcotic analgesic treatment is less than 12 months; or

(iii) first application for treatment beyond 12 months of chronic severe disabling pain not responding to non-narcotic analgesics where the patient’s pain management has been reviewed through consultation by the patient with another medical practitioner, and the clinical need for continuing narcotic analgesic treatment has been confirmed. The date of the consultation must be no more than 3 months prior to the application for a PBS authority. The full name of the medical practitioner consulted and the date of consultation are to be provided at the time of application; or

(iv) subsequent application for treatment of chronic severe disabling pain not responding to non-narcotic analgesics where a PBS authority prescription for treatment beyond 12 months has previously been issued for this patient.

Note
Fentanyl transdermal patches are not recommended in opioid naive patients with non-cancer pain, because of a high incidence of adverse events in these patients. Patients with cancer pain may be initiated on the lowest strength patch (12 micrograms per hour).

Pharmaceutical benefits that have the forms fentanyl transdermal patch 12.375 mg, fentanyl transdermal patch 7.65 mg and fentanyl transdermal patch 12.6 mg (all releasing approximately 75 micrograms per hour) are equivalent for the purposes of substitution.

Diphenylpropylamine derivatives

METHADONE
Restricted benefit
Severe disabling pain not responding to non-narcotic analgesics

Caution
The risk of drug dependence is high.

Note
Authorities for increased maximum quantities and/or repeats will be granted only for:

(i) severe disabling pain associated with proven malignant neoplasia; or

(ii) chronic severe disabling pain not responding to non-narcotic analgesics where the total duration of narcotic analgesic treatment is less than 12 months; or
NERVOUS SYSTEM

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<th>Max. Qty (Packs)</th>
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<th>Premium $</th>
<th>Dispensed Price for Max. Qty $</th>
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**Oripavine derivatives**

**BUPRENORPHINE**

**Restricted benefit**

Chronic severe disabling pain not responding to non-narcotic analgesics

**Caution**

The risk of drug dependence is high.

**Note**

Authorities for increased maximum quantities and/or repeats will be granted only for:

(i) chronic severe disabling pain associated with proven malignant neoplasia; or

(ii) chronic severe disabling pain not responding to non-narcotic analgesics where the total duration of narcotic analgesic treatment is less than 12 months; or

(iii) first application for treatment beyond 12 months of chronic severe disabling pain not responding to non-narcotic analgesics where the patient’s pain management has been reviewed through consultation by the patient with another medical practitioner, and the clinical need for continuing narcotic analgesic treatment has been confirmed. The date of the consultation must be no more than 3 months prior to the application for a PBS authority. The full name of the medical practitioner consulted and the date of consultation are to be provided at the time of application; or

(iv) subsequent application for treatment of chronic severe disabling pain not responding to non-narcotic analgesics where a PBS authority prescription for treatment beyond 12 months has previously been issued for this patient.

**Note**

Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

8866P NP | buprenorphine 10 microgram/hour patch, 2 | 1 ... ... | 41.11 | 36.90 | Norspan | MF |
| 8867Q NP | buprenorphine 20 microgram/hour patch, 2 | 1 ... ... | 56.42 | 36.90 | Norspan | MF |
| 8865N NP | buprenorphine 5 microgram/hour patch, 2 | 1 ... ... | 27.04 | 28.19 | Norspan | MF |

**Other opioids**

**TAPENTADOL**

**Restricted benefit**

Chronic severe disabling pain

**Clinical criteria:**

The condition must be unresponsive to non-narcotic analgesics.

**Caution**

The risk of drug dependence is high.

**Note**

Authorities for increased maximum quantities and/or repeats will be granted only for:

(i) chronic severe disabling pain associated with proven malignant neoplasia; or

(ii) chronic severe disabling pain not responding to non-narcotic analgesics where the total duration of narcotic analgesic treatment is less than 12 months; or

(iii) first application for treatment beyond 12 months of chronic severe disabling pain not responding to non-narcotic analgesics where the patient’s pain management has been reviewed through consultation by the patient with another medical practitioner, and the clinical need for continuing narcotic analgesic treatment has been confirmed. The date of the consultation must be no more than 3 months prior to the application for a PBS authority. The full name of the medical practitioner consulted and the date of consultation are to be provided at the time of application; or

(iv) subsequent application for treatment of chronic severe disabling pain not responding to non-narcotic analgesics where a PBS authority prescription for treatment beyond 12 months has previously been issued for this patient.
authority. The full name of the medical practitioner consulted and the date of consultation are to be provided at the time of application; or
(iv) subsequent application for treatment of chronic severe disabling pain not responding to non-narcotic analgesics where a PBS authority
prescription for treatment beyond 12 months has previously been issued for this patient.

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**TRAMADOL**

**Restricted benefit**

For pain where aspirin and/or paracetamol alone are inappropriate or have failed

**Note**

Authorities for increased maximum quantities and/or repeats will be granted only for severe disabling pain not responding to non-narcotic analgesics.

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<tr>
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### TRAMADOL

**Restricted benefit**

Short-term treatment of acute pain

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**Note**

No applications for increased maximum quantities and/or repeats will be authorised.

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**Note**

No applications for increased maximum quantities and/or repeats will be authorised.
### NERVOUS SYSTEM

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#### OTHER ANALGESICS AND ANTIPYRETICS

### Salicylic acid and derivatives

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#### Anilides

#### PARACETAMOL

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#### PARACETAMOL

### Restricted benefit

#### Chronic arthropathies

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## PARACETAMOL

**Restricted benefit**

Relief of persistent pain associated with osteoarthritis

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## Other analgesics and antipyretics

### PREGABALIN

**Authority required (STREAMLINED)**

4172

Neuropathic pain

**Clinical criteria:**

The condition must be refractory to treatment with other drugs.

**Note**

**Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

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## ANTIMIGRAINE PREPARATIONS

### Selective serotonin (SHT1) agonists

#### ELETRIPTAN

**Authority required (STREAMLINED)**

4573

Migraine attack

**Clinical criteria:**

The condition must have usually failed to respond to analgesics in the past.

**Caution**

Selective serotonin (SHT1) agonists are contraindicated in patients with known or suspected coronary artery disease. The drug should not be used within 24 hours of ergotamine or dihydroergotamine use.

**Note**

No increase in the maximum quantity or number of units may be authorised.

**Note**

No increase in the maximum number of repeats may be authorised.

**Note**

**Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

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#### NARATRIPTAN

**Authority required**

Migraine attack

**Clinical criteria:**

The condition must have usually failed to respond to analgesics in the past.

**Caution**

Selective serotonin (SHT1) agonists are contraindicated in patients with known or suspected coronary artery disease. The drug should not be used...
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NERVOUS SYSTEM

SUMATRIPTAN
Authority required (STREAMLINED)
4558
Migraine attack

Clinical criteria:
The condition must have usually failed to respond to analgesics in the past.

Caution
Selective serotonin (5HT1) agonists are contraindicated in patients with known or suspected coronary artery disease. The drug should not be used within 24 hours of ergotamine or dihydroergotamine use.

Note
No increase in the maximum quantity or number of units may be authorised.

Note
No increase in the maximum number of repeats may be authorised.

Note
Pharmaceutical benefits that have the form sumatriptan tablet 50 mg (as succinate) and pharmaceutical benefits that have the form sumatriptan tablet (fast disintegrating) 50 mg (as succinate) are equivalent for the purposes of substitution.

Note
Continuing Therapy Only:
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ZOLMITRIPTAN
Authority required (STREAMLINED)
4573
Migraine attack

Clinical criteria:
The condition must have usually failed to respond to analgesics in the past.

Caution
Selective serotonin (5HT1) agonists are contraindicated in patients with known or suspected coronary artery disease. The drug should not be used within 24 hours of ergotamine or dihydroergotamine use.

Note
No increase in the maximum quantity or number of units may be authorised.

Note
NERVOUS SYSTEM

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Note

Continuing Therapy Only:

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8266C  
NP  
zolmitriptan 2.5 mg tablet, 2  2  5  ..  26.18  27.33  a Zoltrip  QA

Other antimigraine preparations

CYPROHEPTADINE

Restricted benefit

Prevention of migraine

Note

Cyproheptadine hydrochloride is not PBS-subsidised for use in hay fever or atopy.

Note

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

1798P  
NP  
cyproheptadine hydrochloride 4 mg tablet, 100  1  2  ..  14.53  15.68  Periactin  AS

PIZOTifen

Note

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

3074T  
NP  
pizotifen 500 microgram tablet, 100  1  2  ..  22.09  23.24  Sandomigran 0.5  NV

ANTIEPILEPTICS

ANtiEpileptics

Barbiturates and derivatives

PHENOBARBITONE

Restricted benefit

Epilepsy

Note

Continuing Therapy Only:

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1850J  
NP  
phenobarbitone 30 mg tablet, 200  1  4  ..  16.94  18.09  Aspen Pharma Pty Ltd  QA

2138M  
NP  
phenobarbitone sodium 219 mg/mL injection, 5 x 1 mL ampoules  1  ..  ..  39.36  36.90  Fawns and McAllan Proprietary Limited  FM

PRIMIDONE

Note

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

1939C  
NP  
primidone 250 mg tablet, 200  1  2  ..  83.83  36.90  Mysoline  LM

HydantoIn derivatives

PHENyTOIn

Note

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

2692Q  
NP  
phenytoin 30 mg/5 mL oral liquid, 500  1  3  ..  30.62  31.77  Dilantin  PF
<table>
<thead>
<tr>
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<th>Name, Restriction, Manner of Administration and Form</th>
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<th>No. of Rpts</th>
<th>Premium $</th>
<th>Dispensed Price for Max. Qty $</th>
<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>NP</td>
<td>phenytoin 50 mg tablet: chewable, 200</td>
<td>1</td>
<td>2</td>
<td>...</td>
<td>48.49</td>
<td>36.90</td>
<td>Dilantin Infatabs PF</td>
</tr>
<tr>
<td>NP</td>
<td>phenytoin sodium 100 mg capsule, 200</td>
<td>1</td>
<td>2</td>
<td>...</td>
<td>30.46</td>
<td>31.61</td>
<td>Dilantin Sodium PF</td>
</tr>
<tr>
<td>NP</td>
<td>phenytoin sodium 30 mg capsule, 200</td>
<td>1</td>
<td>2</td>
<td>...</td>
<td>29.52</td>
<td>30.67</td>
<td>Dilantin Sodium PF</td>
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</tbody>
</table>

### Succinimide derivatives

**ETHOSUXIMIDE**

**Note**
Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

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<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>NP</td>
<td>ethosuximide 250 mg capsule, 200</td>
<td>1</td>
<td>2</td>
<td>...</td>
<td>66.18</td>
<td>36.90</td>
<td>Zarontin PF</td>
</tr>
<tr>
<td>NP</td>
<td>ethosuximide 250 mg/5 mL oral liquid, 200 mL</td>
<td>‡1</td>
<td>5</td>
<td>...</td>
<td>29.43</td>
<td>30.38</td>
<td>Zarontin PF</td>
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</table>

### Benzodiazepine derivatives

**CLONAZEPAM**

**Restricted benefit**
Epilepsy

**Note**
Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

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<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>NP</td>
<td>clonazepam 1 mg/mL injection [5 x 1 mL ampoules] (§) inert substance diluent [5 x 1 mL ampoules], 1 pack</td>
<td>1</td>
<td>..</td>
<td>..</td>
<td>18.92</td>
<td>20.07</td>
<td>Rivotril RO</td>
</tr>
</tbody>
</table>

**CLONAZEPAM**

**Authority required**
Neurologically proven epilepsy

**Caution**
Abuse of clonazepam has been reported. Refer to the current product information.

**Note**
Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

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<th>Dispensed Price for Max. Qty $</th>
<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>NP</td>
<td>clonazepam 2 mg tablet, 100</td>
<td>2</td>
<td>2</td>
<td>..</td>
<td>*31.40</td>
<td>a Paxam 2 AF</td>
<td></td>
</tr>
<tr>
<td>NP</td>
<td>clonazepam 2.5 mg/mL oral liquid, 10 mL</td>
<td>2</td>
<td>..</td>
<td>..</td>
<td>*35.26</td>
<td>a Rivotril RO</td>
<td></td>
</tr>
<tr>
<td>NP</td>
<td>clonazepam 500 microgram tablet, 100</td>
<td>2</td>
<td>2</td>
<td>..</td>
<td>*19.84</td>
<td>a Paxam 0.5 AF</td>
<td></td>
</tr>
</tbody>
</table>

**NITRAZEPAM**

**Authority required**
Myoclonic epilepsy

**Authority required**
Malignant neoplasia (late stage)

**Authority required**
For use by patients who are receiving long-term nursing care on account of age, infirmity or other condition in hospitals, nursing homes or residential facilities who have been demonstrated, within the past 6 months, to be benzodiazepine dependent by an unsuccessful attempt at gradual withdrawal

**Authority required**
For use by a patient who is receiving long-term nursing care and in respect of whom a Carer Allowance is payable as a disabled adult and who has been demonstrated, within the past 6 months, to be benzodiazepine dependent by an unsuccessful attempt at gradual withdrawal

**Note**
Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

2732T
**Nitrazepam 5 mg tablet, 25**

- Max. Qty (Packs): 2
- No. of Rpts: 5
- Dispensed Price for Max. Qty $: 10.46
- Premium $: 2.92
- Maximum Recordable Value for Safety Net $: 11.61

<table>
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<th>Max. Qty</th>
<th>No. of Rpts</th>
<th>Premium $</th>
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<tbody>
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<td>2732T</td>
<td>Nitrazepam 5 mg tablet, 25</td>
<td>2</td>
<td>5</td>
<td>10.46</td>
<td>2.92</td>
</tr>
</tbody>
</table>

* Carboxamide derivatives

**Carbamazepine**

**Note**

For item codes 2422L and 1708X, pharmaceutical benefits that have the form tablet 100 mg are equivalent for the purposes of substitution.

**Note**

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

2422L
**Carbamazepine Tablet 100 mg, 100**

- Max. Qty (Packs): 2
- No. of Rpts: 2
- Dispensed Price for Max. Qty $: 18.84
- Premium $: 2.96

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>Dispensed Price for Max. Qty $</th>
</tr>
</thead>
<tbody>
<tr>
<td>2422L</td>
<td>Carbamazepine Tablet 100 mg, 100</td>
<td>2</td>
<td>2</td>
<td>18.84</td>
<td>2.96</td>
</tr>
</tbody>
</table>

1708X
**Carbamazepine 100 mg tablet, 200**

- Max. Qty (Packs): 1
- No. of Rpts: 2
- Dispensed Price for Max. Qty $: 18.82
- Premium $: 2.96
- Maximum Recordable Value for Safety Net $: 19.97

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>Dispensed Price for Max. Qty $</th>
</tr>
</thead>
<tbody>
<tr>
<td>1708X</td>
<td>Carbamazepine 100 mg tablet, 200</td>
<td>1</td>
<td>2</td>
<td>18.82</td>
<td>2.96</td>
</tr>
</tbody>
</table>

**Carbamazepine**

**Note**

For item codes 5039F and 1755J, pharmaceutical benefits that have the form tablet 100 mg are equivalent for the purposes of substitution.

5039F
**Carbamazepine Tablet 100 mg, 100**

- Max. Qty (Packs): 2
- No. of Rpts: 2
- Dispensed Price for Max. Qty $: 18.84
- Premium $: 2.96

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty</th>
<th>No. of Rpts</th>
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<th>Dispensed Price for Max. Qty $</th>
</tr>
</thead>
<tbody>
<tr>
<td>5039F</td>
<td>Carbamazepine Tablet 100 mg, 100</td>
<td>2</td>
<td>2</td>
<td>18.84</td>
<td>2.96</td>
</tr>
</tbody>
</table>

1755J
**Carbamazepine 100 mg tablet, 200**

- Max. Qty (Packs): 1
- No. of Rpts: 2
- Dispensed Price for Max. Qty $: 18.82
- Premium $: 2.96
- Maximum Recordable Value for Safety Net $: 19.97

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>Dispensed Price for Max. Qty $</th>
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</thead>
<tbody>
<tr>
<td>1755J</td>
<td>Carbamazepine 100 mg tablet, 200</td>
<td>1</td>
<td>2</td>
<td>18.82</td>
<td>2.96</td>
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</tbody>
</table>

**Carbamazepine**

**Note**

For item codes 2419H and 1706T, pharmaceutical benefits that have the form tablet 200 mg are equivalent for the purposes of substitution.

**Note**

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

1706T
**Carbamazepine Tablet 200 mg, 100**

- Max. Qty (Packs): 2
- No. of Rpts: 2
- Dispensed Price for Max. Qty $: 29.34
- Premium $: 2.96
- Maximum Recordable Value for Safety Net $: 30.49

<table>
<thead>
<tr>
<th>Code</th>
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<th>No. of Rpts</th>
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</thead>
<tbody>
<tr>
<td>1706T</td>
<td>Carbamazepine Tablet 200 mg, 100</td>
<td>2</td>
<td>2</td>
<td>29.34</td>
<td>2.96</td>
</tr>
</tbody>
</table>

2419H
**Carbamazepine 200 mg tablet, 200**

- Max. Qty (Packs): 1
- No. of Rpts: 2
- Dispensed Price for Max. Qty $: 29.33
- Premium $: 2.96
- Maximum Recordable Value for Safety Net $: 30.48

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>Dispensed Price for Max. Qty $</th>
</tr>
</thead>
<tbody>
<tr>
<td>2419H</td>
<td>Carbamazepine 200 mg tablet, 200</td>
<td>1</td>
<td>2</td>
<td>29.33</td>
<td>2.96</td>
</tr>
</tbody>
</table>

**Carbamazepine**

**Note**

For item codes 5040G and 1724R, pharmaceutical benefits that have the form tablet 200 mg are equivalent for the purposes of substitution.

**Note**

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

1724R
**Carbamazepine Tablet 200 mg, 100**

- Max. Qty (Packs): 2
- No. of Rpts: 2
- Dispensed Price for Max. Qty $: 29.34
- Premium $: 2.96
- Maximum Recordable Value for Safety Net $: 30.49

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty</th>
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</tr>
</thead>
<tbody>
<tr>
<td>1724R</td>
<td>Carbamazepine Tablet 200 mg, 100</td>
<td>2</td>
<td>2</td>
<td>29.34</td>
<td>2.96</td>
</tr>
</tbody>
</table>

5040G
**Carbamazepine 200 mg tablet, 200**

- Max. Qty (Packs): 1
- No. of Rpts: 2
- Dispensed Price for Max. Qty $: 29.33
- Premium $: 2.96
- Maximum Recordable Value for Safety Net $: 30.48

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>Dispensed Price for Max. Qty $</th>
</tr>
</thead>
<tbody>
<tr>
<td>5040G</td>
<td>Carbamazepine 200 mg tablet, 200</td>
<td>1</td>
<td>2</td>
<td>29.33</td>
<td>2.96</td>
</tr>
</tbody>
</table>

**Carbamazepine**

**Note**

For item codes 2427R and 2426Q, pharmaceutical benefits that have the form tablet 200 mg are equivalent for the purposes of substitution.

**Note**

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

2427R
**Carbamazepine 100 mg/5 mL oral liquid, 300 mL**

- Max. Qty (Packs): 1
- No. of Rpts: 5
- Dispensed Price for Max. Qty $: 21.69
- Maximum Recordable Value for Safety Net $: 22.84

<table>
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<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
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<th>No. of Rpts</th>
<th>Premium $</th>
<th>Dispensed Price for Max. Qty $</th>
</tr>
</thead>
<tbody>
<tr>
<td>2427R</td>
<td>Carbamazepine 100 mg/5 mL oral liquid, 300 mL</td>
<td>1</td>
<td>5</td>
<td>21.69</td>
<td>2.96</td>
</tr>
</tbody>
</table>

2426Q
**Carbamazepine 200 mg tablet: modified release, 200 tablets**

- Max. Qty (Packs): 1
- No. of Rpts: 2
- Dispensed Price for Max. Qty $: 29.82
- Maximum Recordable Value for Safety Net $: 30.97

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
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</thead>
<tbody>
<tr>
<td>2426Q</td>
<td>Carbamazepine 200 mg tablet: modified release, 200 tablets</td>
<td>1</td>
<td>2</td>
<td>29.82</td>
<td>2.96</td>
</tr>
</tbody>
</table>

2431Y
**Carbamazepine 400 mg tablet: modified release, 200 tablets**

- Max. Qty (Packs): 1
- No. of Rpts: 2
- Dispensed Price for Max. Qty $: 49.37
- Maximum Recordable Value for Safety Net $: 36.90

<table>
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<th>No. of Rpts</th>
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</thead>
<tbody>
<tr>
<td>2431Y</td>
<td>Carbamazepine 400 mg tablet: modified release, 200 tablets</td>
<td>1</td>
<td>2</td>
<td>49.37</td>
<td>2.96</td>
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</table>
### NERVOUS SYSTEM

#### CARBAMAZEPINE

<table>
<thead>
<tr>
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<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>5041H</td>
<td>carbamazepine 100 mg/5 mL oral liquid, 300 mL</td>
<td>2</td>
<td>3</td>
<td>21.69</td>
<td>22.84</td>
<td>22.84</td>
<td>Tegretol Liquid NV</td>
</tr>
<tr>
<td>503E</td>
<td>carbamazepine 200 mg tablet: modified release, 200 tablets</td>
<td>1</td>
<td>5</td>
<td>29.82</td>
<td>30.97</td>
<td>30.97</td>
<td>Tegretol CR 200 NV</td>
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<tr>
<td>5037D</td>
<td>carbamazepine 400 mg tablet: modified release, 200 tablets</td>
<td>1</td>
<td>5</td>
<td>49.37</td>
<td>36.90</td>
<td>36.90</td>
<td>Tegretol CR 400 NV</td>
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</tbody>
</table>

#### OXCARBAZEPINE

**Authority required (STREAMLINED)**

1587

Treatment of partial epileptic seizures and primary generalised tonic-clonic seizures, which are not controlled satisfactorily by other anti-epileptic drugs

**Note**

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

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<th>Brand Name and Manufacturer</th>
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<tbody>
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<td>8584T</td>
<td>oxcarbazepine 150 mg tablet, 100</td>
<td>1</td>
<td>5</td>
<td>72.61</td>
<td>36.90</td>
<td>36.90</td>
<td>Trileptal NV</td>
</tr>
<tr>
<td>8585W</td>
<td>oxcarbazepine 300 mg tablet, 100</td>
<td>1</td>
<td>5</td>
<td>115.42</td>
<td>36.90</td>
<td>36.90</td>
<td>Trileptal NV</td>
</tr>
<tr>
<td>8588B</td>
<td>oxcarbazepine 60 mg/mL oral liquid, 250 mL</td>
<td>2</td>
<td>5</td>
<td>*138.46</td>
<td>36.90</td>
<td>36.90</td>
<td>Trileptal NV</td>
</tr>
<tr>
<td>8586X</td>
<td>oxcarbazepine 600 mg tablet, 100</td>
<td>1</td>
<td>5</td>
<td>188.32</td>
<td>36.90</td>
<td>36.90</td>
<td>Trileptal NV</td>
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</table>

#### Fatty acid derivatives

#### TIAGABINE

**Authority required (STREAMLINED)**

2664

Treatment of partial epileptic seizures which are not controlled satisfactorily by other anti-epileptic drugs

**Note**

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

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<th>No. of Rpts</th>
<th>Dispensed Price for Max. Qty $</th>
<th>Premium $</th>
<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>8222R</td>
<td>tiagabine 10 mg tablet, 50</td>
<td>2</td>
<td>5</td>
<td>*139.18</td>
<td>36.90</td>
<td>36.90</td>
<td>Gabitril OA</td>
</tr>
<tr>
<td>8223T</td>
<td>tiagabine 15 mg tablet, 50</td>
<td>2</td>
<td>5</td>
<td>*197.24</td>
<td>36.90</td>
<td>36.90</td>
<td>Gabitril OA</td>
</tr>
<tr>
<td>8221Q</td>
<td>tiagabine 5 mg tablet, 50</td>
<td>2</td>
<td>5</td>
<td>*72.96</td>
<td>36.90</td>
<td>36.90</td>
<td>Gabitril OA</td>
</tr>
</tbody>
</table>

#### VALPROATE

**Caution**

There are reports of fatal hepatotoxicity, particularly in children.

There is increasing evidence of dose-related teratogenesis from this drug.

**Note**

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
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<th>No. of Rpts</th>
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<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>2294R</td>
<td>valproate sodium 100 mg tablet, 100</td>
<td>2</td>
<td>2</td>
<td>*32.34</td>
<td>33.49</td>
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<td>Epilim SW</td>
</tr>
<tr>
<td>2289L</td>
<td>valproate sodium 200 mg tablet: enteric, 100</td>
<td>2</td>
<td>2</td>
<td>25.46</td>
<td>26.61</td>
<td></td>
<td>Sodium Valproate SW Sandoz</td>
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<tr>
<td></td>
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### VIGABATRIN

**Authority required (STREAMLINED)**

1426

Treatment of epileptic seizures which are not controlled satisfactorily by other anti-epileptic drugs

**Caution**

Visual field defects have been reported with this drug.

**Note**

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

### Other antiepileptics

**GABAPENTIN**

**Authority required (STREAMLINED)**

2664

Treatment of partial epileptic seizures which are not controlled satisfactorily by other anti-epileptic drugs

**Note**

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.
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**LACOSAMIDE**

**Authority required (STREAMLINED)**

4271

Intractable partial epileptic seizures

**Clinical criteria:**

The treatment must be in combination with two or more anti-epileptic drugs which includes one second-line adjunctive agent,

AND

The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs, which includes at least one first-line anti-epileptic agent and at least two second-line adjunctive anti-epileptic agents,

AND

The treatment must be for dose titration purposes.

**Population criteria:**

Patient must be aged 16 years or older.

**Treatment criteria:**

Must be treated by a neurologist.

**Note**

**Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

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**LACOSAMIDE**

**Authority required (STREAMLINED)**

4264

Intractable partial epileptic seizures

**Clinical criteria:**

The treatment must be in combination with two or more anti-epileptic drugs which includes one second-line adjunctive agent,

AND

The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs, which includes at least one first-line anti-epileptic agent and at least two second-line adjunctive anti-epileptic agents.

**Population criteria:**

Patient must be aged 16 years or older.

**Treatment criteria:**

Must be treated by a neurologist.
## NERVOUS SYSTEM

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**NERVOUS SYSTEM**

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**LEVETIRACETAM**

**Authority required (STREAMLINED)**

2664

Treatment of partial epileptic seizures which are not controlled satisfactorily by other anti-epileptic drugs

**Note**

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.
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**TOPIRAMATE**

**Authority required (STREAMLINED)**

2797

Treatment of partial epileptic seizures, primary generalised tonic-clonic epileptic seizures and seizures of the Lennox-Gastaut syndrome, which are not controlled satisfactorily by other anti-epileptic drugs

**Authority required (STREAMLINED)**

2799

Prophylaxis of migraine in a patient who has experienced an average of 3 or more migraines per month over a period of at least 6 months, and who:

(a) has a contraindication to beta-blockers, as described in the relevant TGA-approved Product Information; OR
(b) has experienced intolerance of a severity necessitating permanent withdrawal during treatment with a beta-blocker; AND
(c) has a contraindication to pizotifen because the weight gain associated with this drug poses an unacceptable risk; OR
(d) has experienced intolerance of a severity necessitating permanent withdrawal during treatment with pizotifen.

Details of the contraindication and/or intolerance(s) must be documented in the patient’s medical records when treatment is initiated

**Note**

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8163P NP  
topiramate 25 mg tablet, 60  
1  
5  
..  
26.52  
27.67  
a  
APO-Topiramate TX  
a  
Epiramax 25 QA  
a  
RBX Topiramate RA  
a  
Tamate AF  
a  
Topamox JC  
a  
Topiramate-GA GN  
a  
Topiramate GH GQ  
a  
Topiramate Sandoz SZ  
a  
APO-Topiramate TX  

8164Q NP  
topiramate 50 mg tablet, 60  
1  
5  
..  
39.20  
36.90  
a  
Epiramax 50 QA  
a  
RBX Topiramate RA  
a  
Tamate AF  
a  
Topamox JC  
a  
Topiramate-GA GN  
a  
Topiramate GH GQ  
a  
Topiramate Sandoz SZ  

**ZONISAMIDE**

**Authority required (STREAMLINED)**

2664

Treatment of partial epileptic seizures which are not controlled satisfactorily by other anti-epileptic drugs

**Note**

Continuing Therapy Only:

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9390F NP  
zonisamide 100 mg capsule, 56  
2  
5  
..  
*93.80  
36.90  
Zonegran SA  

9388D NP  
zonisamide 25 mg capsule, 56  
1  
5  
..  
23.14  
24.29  
Zonegran SA  

9389E NP  
zonisamide 50 mg capsule, 56  
1  
5  
..  
34.06  
35.21  
Zonegran SA  

**ANTI-PARKINSON DRUGS**

**ANTICHOLINERGIC AGENTS**

**Tertiary amines**

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<td>Maintenance therapy following treatment which was commenced in a hospital-based movement disorder clinic, of a patient with advanced</td>
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*Note: Values marked with an asterisk (*) include a prescription fee. Additional charges may apply for the use of this medication.*
<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
<th>Premium $</th>
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<th>Brand Name and Manufacturer</th>
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<td>36.90</td>
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<td>9345W</td>
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<td>Stalevo 125/31.25/200mg NV</td>
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<td>*325.46</td>
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**Adamantane derivatives**

**AMANTADINE**

**Restricted benefit**

Parkinson's disease which is not drug induced

**Note**

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.
### NERVOUS SYSTEM

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#### Dopamine agonists

**BROMOCRIPTINE**

**Restricted benefit**

- Acromegaly
- Parkinson’s disease

**Restricted benefit**

- Pathological hyperprolactinaemia where surgery is not indicated
- Pathological hyperprolactinaemia where surgery has already been used with incomplete resolution
- Pathological hyperprolactinaemia where radiotherapy is not indicated
- Pathological hyperprolactinaemia where radiotherapy has already been used with incomplete resolution

**Note**

Care should be taken when treating patients with advanced age and significant cognitive impairment with dopamine agonists.

**Note**

For item codes 1443Y and 1559C, pharmaceutical benefits that have the form tablet 2.5 mg (base) are equivalent for the purposes of substitution.

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<th>Maximum Recordable Value for Safety Net $</th>
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**CABERGOLINE**

**Restricted benefit**

Parkinson's disease

**Note**

Care should be taken when treating patients with advanced age and significant cognitive impairment with dopamine agonists.

**Note**

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**PRAMIPEXOLE**

**Restricted benefit**

Parkinson disease

**Caution**

Episodes of sudden onset of sleep without warning, during activity, have been reported with this drug.

**Note**

Care should be taken when treating patients with advanced age and significant cognitive impairment with dopamine agonists.

**Note**

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</table>
### PRAMIPEXOLE

**Restricted benefit**

**Parkinson disease**

**Caution**  
Episodes of sudden onset of sleep without warning, during activity, have been reported with this drug.

**Note**  
Care should be taken when treating patients with advanced age and significant cognitive impairment with dopamine agonists.

**Note**  
No applications for increased maximum quantities and/or repeats will be approved for extended release pramipexole formulations.

**Note**  
Continuing Therapy Only:

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<td>34.29</td>
<td>Sifrol ER</td>
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</table>

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**PRAMIPEXOLE**  
**Restricted benefit**

Treatment of severe primary Restless Legs Syndrome in a patient who manifests all 4 diagnostic criteria below and whose baseline International Restless Legs Syndrome Rating Scale (IRLSRS) score is greater than or equal to 21 points prior to initiation of pramipexole.

The date and IRLSRS score must be documented in the patient’s medical records at the time pramipexole treatment is initiated.

The diagnostic criteria for Restless Legs Syndrome are:

(a) An urge to move the legs usually accompanied or caused by unpleasant sensations in the legs; and  
(b) The urge to move or unpleasant sensations begin or worsen during periods of rest or inactivity such as lying or sitting; and  
(c) The urge to move or unpleasant sensations are partially or totally relieved by movement, such as walking or stretching, at least as long as the activity continues; and  
(d) The urge to move or unpleasant sensations are worse in the evening or night than during the day or only occur during the evening or night.

Pramipexole is not PBS-subsidised for Restless Legs Syndrome secondary to other causes

**Caution**  
Episodes of sudden onset of sleep without warning, during activity, have been reported with this drug.

**Note**  
Care should be taken when treating patients with advanced age and significant cognitive impairment with dopamine agonists.

**Note**  
No applications for increased maximum quantities and/or repeats will be authorised.

**Note**  
Continuing Therapy Only:

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<tr>
<td>9393J</td>
<td>pramipexole hydrochloride monohydrate 125 microgram tablet, 30</td>
<td>1 2 ..</td>
<td>11.23</td>
<td>12.38</td>
<td>Sifrol</td>
<td>BY</td>
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<tr>
<td>9394K</td>
<td>pramipexole hydrochloride monohydrate 250 microgram tablet, 100</td>
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<td>36.07</td>
<td>36.90</td>
<td>Sifrol</td>
<td>BY</td>
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**ROTIGOTINE**

**Restricted benefit**

**Parkinson disease**

**Clinical criteria:**
The treatment must be as adjunctive therapy to a levodopa-decarboxylase inhibitor combination.

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<td>rotigotine 2 mg/24 hours patch, 28</td>
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<td>36.90</td>
<td>Neupro</td>
<td>UC</td>
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**ROTIGOTINE**

**Restricted benefit**

**Parkinson disease**

**Clinical criteria:**
The treatment must be as adjunctive therapy to a levodopa-decarboxylase inhibitor combination.

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**Monoamine oxidase B inhibitors**

**RASAGILINE**

**Authority required (STREAMLINED)**

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<td>1952R</td>
<td>RASAGILINE Tablet 1 mg (as mesilate), 30</td>
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<td>Azilect</td>
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**SELEGILINE**

**Restricted benefit**

Late stage Parkinson’s disease as adjunctive therapy in patients being treated with levodopa—decarboxylase inhibitor combinations

**Note**

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

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<td>selegiline hydrochloride 5 mg tablet, 100</td>
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**Other dopaminergic agents**

**ENTACAPONE**

**Authority required (STREAMLINED)**

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<td>entacapone 200 mg tablet, 100</td>
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<td>1196V NP</td>
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<td>SW</td>
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<td>1199D NP</td>
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<td>1197B NP</td>
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<td>1201F NP</td>
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<td>1195X NP</td>
<td>chlorpromazine hydrochloride 50 mg/2 mL injection, 10 x 2 mL ampoules</td>
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<td>20.82 21.97</td>
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<td>FLUPHENAZINE DECANOATE</td>
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<td>1046C NP</td>
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<td>3098C NP</td>
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<td>26.72 27.87</td>
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<td>37.99 36.90</td>
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<td>2185B NP</td>
<td>trifluoperazine 1 mg tablet, 100</td>
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<td>2386N NP</td>
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<td>2767P NP</td>
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### NERVOUS SYSTEM

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<td>haloperidol 2 mg/mL oral liquid, 100 mL</td>
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<td>NP 2770T</td>
<td>haloperidol 5 mg tablet, 50</td>
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<td>NP 2768Q</td>
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<td>NP 2761H</td>
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<td>NP 2766N</td>
<td>haloperidol (as decanoate) 150 mg/3 mL injection, 5 x 3 mL ampoules</td>
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<td>NP 2765M</td>
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<td>28.16</td>
<td>Haldol decanoate JC</td>
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</table>

**HALOPERIDOL DECANOATE**

**Note**

Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

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<td>ziprasidone 20 mg capsule, 60</td>
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<td>NP 9071K</td>
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**Indole derivatives**

**ZIPRASIDONE**

*Authority required (STREAMLINED)*

**1589**

Schizophrenia

*Authority required (STREAMLINED)*

**3084**

Monotherapy, for up to 6 months, of an episode of acute mania or mixed episodes associated with bipolar I disorder

**Note**

Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

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<tbody>
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<td>NP 2257T</td>
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<td>NP 2255Q</td>
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**THIOXANTHENE DERIVATIVES**

**FLUPENTHILOX DECANOATE**

**Note**

Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

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**Diazepines, oxazepines, thiazepines and oxepines**
## NERVOUS SYSTEM

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<td></td>
<td>Treatment, for up to 6 months, of an episode of acute mania or mixed episodes associated with bipolar I disorder</td>
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<td>Note</td>
<td>Shared Care Model: For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.</td>
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<td>5141N</td>
<td>asenapine 10 mg wafer: sublingual, 60</td>
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<td>5140M</td>
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<td>Note</td>
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## NERVOUS SYSTEM

### OLANZAPINE

**Authority required (STREAMLINED)**

**1589**

Schizophrenia

**Authority required (STREAMLINED)**

**2044**

Maintenance treatment of bipolar I disorder

**Note**

Pharmaceutical benefits that have the form olanzapine tablet 10 mg and pharmaceutical benefits that have the form olanzapine tablet 10 mg (as benzoate) are equivalent for the purposes of substitution.

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**OLANZAPINE**

**Authority required (STREAMLINED)**

**1589**

Schizophrenia

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**2044**

Maintenance treatment of bipolar I disorder

**Note**

Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.
### NERVOUS SYSTEM

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**Note**
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**OLANZAPINE**

Authority required (STREAMLINED)

1589
Schizophrenia

Authority required (STREAMLINED)

2044
Maintenance treatment of bipolar I disorder

**Note**
Pharmaceutical benefits that have the form olanzapine tablet 5 mg (orally disintegrating) and pharmaceutical benefits that have the form olanzapine wafer 5 mg are equivalent for the purposes of substitution.

**Note**

Shared Care Model:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**OLANZAPINE**

Authority required (STREAMLINED)

1589
Schizophrenia

Authority required (STREAMLINED)

2044
Maintenance treatment of bipolar I disorder

**Note**
Pharmaceutical benefits that have the form olanzapine tablet 7.5 mg and pharmaceutical benefits that have the form olanzapine tablet 7.5 mg (as benzoate) are equivalent for the purposes of substitution.

**Note**

Shared Care Model:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.
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**QUETIAPINE**

**Authority required (STREAMLINED)**

1589

Schizophrenia

**Authority required (STREAMLINED)**

2765

Monotherapy, for up to 6 months, of an episode of acute mania associated with bipolar I disorder

**Authority required (STREAMLINED)**

2044

Maintenance treatment of bipolar I disorder

**Note**

Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

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| 8458E  | NP | quetiapine 200 mg tablet, 60 | 1 5 | .. | 116.16 | 36.90 | a APO-Quetiapine TX |

| a      | APO-Quetiapine              | TX   |     |     |       |       |                     |
| a      | Chem mart Quetiapine        | CH   |     |     |       |       |                     |
| a      | Delucon 200                 | DO   |     |     |       |       |                     |
| a      | Pharmacor Quetiapine 200    | CR   |     |     |       |       |                     |
| a      | Pharmacy Choice Quetiapine  | RI   |     |     |       |       |                     |
| a      | Seroquel                    | AP   |     |     |       |       |                     |
| a      | Syquet                      | AF   |     |     |       |       |                     |
| a      | Terry White Chemists Quetiapine Seroquel XR       | TW   |     |     |       |       |                     |
| a      | Chem mart Quetiapine        | CH   |     |     |       |       |                     |
| a      | Delucon 200                 | DO   |     |     |       |       |                     |
| a      | Pharmacor Quetiapine 200    | CR   |     |     |       |       |                     |
| a      | Pharmacy Choice Quetiapine  | RI   |     |     |       |       |                     |
| a      | Seroquel                    | AP   |     |     |       |       |                     |
| a      | Syquet                      | AF   |     |     |       |       |                     |
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498
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**QUETIAPINE**

**Authority required (STREAMLINED)**

4391

Schizophrenia

**Clinical criteria:**

The treatment must be for dose titration purposes.

**Authority required (STREAMLINED)**

4396

Acute mania

**Clinical criteria:**

The condition must be associated with bipolar I disorder,

AND

The treatment must be as monotherapy,

AND

The treatment must be for dose titration purposes.

**Authority required (STREAMLINED)**

4385
Bipolar I disorder

Clinical criteria:

The treatment must be maintenance therapy,

AND

The treatment must be for dose titration purposes.

Note
No increase in the maximum quantity or number of units may be authorised.

Note
No increase in the maximum number of repeats may be authorised.

Note
Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

8456C
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1
.. ..
36.42 36.90
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APO-Quetiapine
TX
a
Chem mart Quetiapine
CH
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Delucon 25
DO
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Pharmacor Quetiapine 25
CR
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Pharmacy Choice Quetiapine
RI
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Quetia 25
FM
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Quetiaccord
UA
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Quetiapine Actavis 25
VN
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Quetiapine AN
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Quetiapine-DRLA
RZ
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GQ
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SZ
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Sequase
PM
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Seronia 25
QA
a
Seroquel
AP
a
Syquet
AF
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Terry White Chemists Quetiapine
TW

Benzamides

AMISULPRIDE

Authority required (STREAMLINED)

1589

Schizophrenia

Note

Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

8594H
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23.27 24.42
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TX
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SW
a Sulpiride
AF
a Solian Solution
SW

8736T
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SW

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SW
### Other antipsychotics

**ARIPIPRAZOLE**

**Authority required (STREAMLINED)**

1589

Schizophrenia

**Note**

Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

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### PALIPERIDONE

**Authority required (STREAMLINED)**

4246

Schizophrenia

**Note**

Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

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### RISPERIDONE

**Authority required (STREAMLINED)**

1589

Schizophrenia

**Authority required (STREAMLINED)**

2272

Adjunctive therapy to mood stabilisers for up to 6 months, of an episode of acute mania associated with bipolar I disorder

**Note**

Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

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Winthrop

a Amisulpride Sandoz

SZ

a APO-Amisulpride

TX

a Solian 400

SW

a Sulpix

AF
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RISPERIDONE

Authority required (STREAMLINED)

2061

Behavioural disturbances characterised by psychotic symptoms and aggression in patients with dementia where non-pharmacological methods have been unsuccessful.

Authority required (STREAMLINED)

3083

Treatment under the supervision of a paediatrician or psychiatrist, in combination with non-pharmacological measures, of severe behavioural disturbances in a patient aged less than 18 years with autism.

Continuing PBS-subsidised treatment under the supervision of a paediatrician or psychiatrist, in combination with non-pharmacological measures, of severe behavioural disturbances in a patient 18 years of age or older with autism who was commenced on PBS-subsidised treatment with risperidone prior to turning 18 years of age.

Behaviour disturbances are defined as severe aggression and injuries to self or others where non-pharmacological methods alone have been unsuccessful.

The diagnosis of autism must be made based on the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) or ICD-10 international classification of mental and behavioural disorders.

Caution

In placebo controlled trials in elderly patients with dementia there was a significantly higher incidence of cerebrovascular adverse events, such as stroke (including fatalities) and transient ischaemic attacks, in patients treated with risperidone compared with patients treated with placebo.

Note

Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

8789N

NP

risperidone 1 mg tablet, 60

1 2 ..

24.07 25.22

Risperdal Quicklet

JC

Risperidone generic health

GQ

Risperidone Sandoz

SZ

Rispernia

ER

Rixadone

AF

8790P

NP

risperidone 1 mg tablet: orally disintegrating, 28

2 2 ..

*26.86 28.01

Risperdal Quicklet

JC

8799D

NP

risperidone 1 mg/mL oral liquid, 100 mL

‡1 2 ..

118.37 36.90

Risperdal

JC

Risperidone 500 microgram tablet:

orally disintegrating, 28

2 2 ..

*16.82 17.97

Risperdal Quicklet

JC

RISPERIDONE

Authority required (STREAMLINED)

3083

Treatment under the supervision of a paediatrician or psychiatrist, in combination with non-pharmacological measures, of severe behavioural disturbances in a patient aged less than 18 years with autism.

Continuing PBS-subsidised treatment under the supervision of a paediatrician or psychiatrist, in combination with non-pharmacological measures, of severe behavioural disturbances in a patient 18 years of age or older with autism who was commenced on PBS-subsidised treatment with risperidone prior to turning 18 years of age.

Behaviour disturbances are defined as severe aggression and injuries to self or others where non-pharmacological methods alone have been unsuccessful.

The diagnosis of autism must be made based on the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) or ICD-10 international classification of mental and behavioural disorders.

Note

Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

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45.70 36.90

APO-Risperidone

TX
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**RISPERIDONE**

**Authority required (STREAMLINED)**

1589

Schizophrenia

**Authority required (STREAMLINED)**

3841

Maintenance treatment, in combination with lithium or sodium valproate, of treatment refractory bipolar I disorder

**Note**

Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

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**RISPERIDONE**

**Authority required (STREAMLINED)**

2061

Behavioural disturbances characterised by psychotic symptoms and aggression in patients with dementia where non-pharmacological methods have been unsuccessful

**Authority required (STREAMLINED)**

3083

Treatment under the supervision of a paediatrician or psychiatrist, in combination with non-pharmacological measures, of severe behavioural disturbances in a patient aged less than 18 years with autism.

Continuing PBS-subsidised treatment under the supervision of a paediatrician or psychiatrist, in combination with non-pharmacological measures, of severe behavioural disturbances in a patient 18 years of age or older with autism who was commenced on PBS-subsidised treatment with risperidone prior to turning 18 years of age.

Behaviour disturbances are defined as severe aggression and injuries to self or others where non-pharmacological methods alone have been unsuccessful.

The diagnosis of autism must be made based on the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) or ICD-10 international classification of mental and behavioural disorders

**Caution**

In placebo controlled trials in elderly patients with dementia there was a significantly higher incidence of cerebrovascular adverse events, such as stroke (including fatalities) and transient ischaemic attacks, in patients treated with risperidone compared with patients treated with placebo.

**Note**

For item codes 8787L and 1842Y, pharmaceutical benefits that have the form tablet 0.5 mg are equivalent for the purposes of substitution.

**Note**

Shared Care Model:
### NERVOUS SYSTEM

**RISPERIDONE**

**Authority required (STREAMLINED)**

**1589**

Schizophrenia

**Note**

For item codes 8869T and 1846E, pharmaceutical benefits that have the form tablet 0.5 mg are equivalent for the purposes of substitution.

**Note**

Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

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### ANXIOLYTICS

**Benzodiazepine derivatives**

**ALPRAZOLAM**

**Authority required**

Panic disorder where other treatments have failed or are inappropriate

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### NERVOUS SYSTEM

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### DIAZEPAM

**Authority required**

Chronic spasticity

**Population criteria:**

Patient must be under 18 years of age.

<table>
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<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
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</table>

### DIAZEPAM

**Note**

Authorities for increased maximum quantities and/or repeats for the oral forms of diazepam will be granted only for

(i) the treatment of disabling spasticity; or

(ii) malignant neoplasia (late stage); or

(iii) use by patients who are receiving long-term nursing care on account of age, infirmity or other condition in hospitals, nursing homes or residential facilities and who have been demonstrated, within the past six months, to be benzodiazepine dependent by an unsuccessful attempt at gradual withdrawal; or

(iv) use by a patient who is receiving long-term nursing care and in respect of whom a Carer Allowance is payable as a disabled adult and who has been demonstrated, within the past six months, to be benzodiazepine dependent by an unsuccessful attempt at gradual withdrawal.

Up to six months' treatment (i.e. one month's treatment with five repeats) may be requested.
## NERVOUS SYSTEM

### Benzodiazepine derivatives

#### NITRAZEPAM

**Note**
Authorities for increased maximum quantities and/or repeats will not be granted except as detailed under the ‘Authority required’ listing of nitrazepam below.

<table>
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<tr>
<th>Code</th>
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#### NITRAZEPAM

**Authority required**
Malignant neoplasia (late stage)

**Authority required**
For use by patients who are receiving long-term nursing care and in respect of whom a Carer Allowance is payable as a disabled adult and who has been demonstrated, within the past 6 months, to be benzodiazepine dependent by an unsuccessful attempt at gradual withdrawal

<table>
<thead>
<tr>
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#### OXAZEPAM

**Note**
 Authorities for increased maximum quantities and/or repeats will not be granted except as detailed under the ‘Authority required’ listing of oxazepam below.

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#### OXAZEPAM

**Authority required**
Malignant neoplasia (late stage)

**Authority required**
For use by patients who are receiving long-term nursing care on account of age, infirmity or other condition in hospitals, nursing homes or residential facilities and who have been demonstrated, within the past 6 months, to be benzodiazepine dependent by an unsuccessful attempt at gradual withdrawal

**Authority required**
For use by a patient who is receiving long-term nursing care and in respect of whom a Carer Allowance is payable as a disabled adult and who has been demonstrated, within the past 6 months, to be benzodiazepine dependent by an unsuccessful attempt at gradual withdrawal

<table>
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#### HYPNOTICS AND SEDATIVES

**Benzodiazepine derivatives**

#### NITRAZEPAM

**Note**
 Authorities for increased maximum quantities and/or repeats will not be granted except as detailed under the ‘Authority required’ listing of nitrazepam below.

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## HYPNOTICS AND SEDATIVES

**Benzodiazepine derivatives**

#### NITRAZEPAM

**Note**
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#### NITRAZEPAM

**Authority required**
Myoclonic epilepsy

**Authority required**
Malignant neoplasia (late stage)

**Authority required**
<table>
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<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
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**NERVOUS SYSTEM**

**PSYCHOANALEPTICS**

**ANTIDEPRESSANTS**

*Non-selective monoamine reuptake inhibitors*

**AMITRIPTYLINE**

**Note**

For use by patients who are receiving long-term nursing care on account of age, infirmity or other condition in hospitals, nursing homes or residential facilities and who have been demonstrated, within the past 6 months, to be benzodiazepine dependent by an unsuccessful attempt at gradual withdrawal

**Authority required**

For use by a patient who is receiving long-term nursing care in respect of whom a Carer Allowance is payable as a disabled adult and who has been demonstrated, within the past 6 months, to be benzodiazepine dependent by an unsuccessful attempt at gradual withdrawal

**Note**

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

---

**Code**

**Name, Restriction, Manner of Administration and Form**

**Max. Qty (Packs)**

**No. of Rpts**

**Premium $**

**Dispensed Price for Max. Qty $**

**Maximum Recordable Value for Safety Net $**

**Brand Name and Manufacturer**

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**AMITRIPTYLINE**

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**AMITRIPTYLINE**

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**NERVOUS SYSTEM**

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**CLOMIPRAMINE**

**Restricted benefit**
Cataplexy associated with narcolepsy

**Restricted benefit**
Obsessive-compulsive disorder

**Restricted benefit**
Phobic disorders in adults

**Note**
Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

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**DOTHEPIN**

**Note**
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## ESCITALOPRAM

### Restricted benefit

Moderate to severe generalised anxiety disorder (GAD), as defined by Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) criteria, in a patient who has not responded to non-pharmacological therapy and for whom a GP Mental Health Care Plan, as described under item 2710 of the Medicare Benefits Schedule, has been prepared.

### Restricted benefit

Moderate to severe generalised anxiety disorder (GAD), as defined by Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) criteria, in a patient who has not responded to non-pharmacological therapy and who has been assessed by a psychiatrist.

### Restricted benefit

Continuing PBS-subsidised treatment, for moderate to severe generalised anxiety disorder (GAD), of a patient commenced on escitalopram prior to 1 March 2008.

### Restricted benefit

Moderate to severe social anxiety disorder (social phobia, SAD), as described by Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) criteria, in a patient who has not responded to non-pharmacological therapy and for whom a GP Mental Health Care Plan, as described under item 2710 of the Medicare Benefits Schedule, has been prepared.

### Restricted benefit

Moderate to severe social anxiety disorder (social phobia, SAD), as described by Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) criteria, in a patient who has not responded to non-pharmacological therapy and who has been assessed by a psychiatrist.

### Restricted benefit

Continuing PBS-subsidised treatment, for moderate to severe social anxiety disorder (social phobia, SAD), of a patient commenced on escitalopram prior to 1 March 2008.

### Restricted benefit

Major depressive disorders.

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**Note**
Pharmaceutical benefits that have the form paroxetine tablet 20 mg (as hydrochloride) and pharmaceutical benefits that have the form paroxetine tablet 20 mg (as mesilate) are equivalent for the purposes of substitution.
### NERVOUS SYSTEM

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**Monoamine oxidase inhibitors, non-selective**

**PHENELZINE**

**Restricted benefit**

Depression where all other anti-depressant therapy has failed or is inappropriate

**Caution**

This drug is an irreversible monoamine oxidase inhibitor.

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**TRANYLCYPROMINE**

**Caution**

This drug is an irreversible monoamine oxidase inhibitor.

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**Monoamine oxidase A inhibitors**

**MOCLOBEMIDE**

**Restricted benefit**

Major depressive disorders

**Note**

Continuing Therapy Only:

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## NERVOUS SYSTEM

### Other antidepressants

**DESVENLAFAXINE**

**Restricted benefit**

Major depressive disorders

**Note**

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**DULOXETINE**

**Restricted benefit**

Major depressive disorders

**Note**

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### LITHIUM CARBONATE

**Note**

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**MIANSERIN**

**Restricted benefit**

Severe depression
Caution
Neutropenia and agranulocytosis are more frequent in the elderly, especially in the early months of therapy.

Note
Continuing Therapy Only:
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MIRTAZAPINE
Restricted benefit
Major depressive disorders

Note
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**REBOXETINE**

**Restricted benefit**

Major depressive disorders

**Note**

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**VENLAFAXINE**

**Restricted benefit**

Major depressive disorders

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PSYCHOSTIMULANTS, AGENTS USED FOR ADHD AND NOOTROPICS
*Centrally acting sympathomimetics*

**ATOMOXETINE**

*Authority required (STREAMLINED)*

4591

**Attention deficit hyperactivity disorder**

**Treatment Phase: Initial treatment**

**Clinical criteria:**

The condition must be or have been diagnosed by a paediatrician or psychiatrist according to the DSM-5 criteria, AND

Patient must have a contraindication to dexamphetamine or methylphenidate as specified in TGA-approved product information; OR

Patient must have a comorbid mood disorder that has developed or worsened as a result of dexamphetamine or methylphenidate treatment and is of a severity necessitating treatment withdrawal; OR

Patient must be at an unacceptable medical risk of a severity necessitating permanent stimulant treatment withdrawal if given a stimulant treatment with another agent; OR

Patient must have experienced adverse reactions of a severity necessitating permanent treatment withdrawal following treatment with dexamphetamine and treatment with methylphenidate (not simultaneously).

**Population criteria:**

Patient must be or have been diagnosed between the ages of 6 and 18 years inclusive.

*Authority required (STREAMLINED)*

4578

**Attention deficit hyperactivity disorder**

**Treatment Phase: Continuing treatment**

**Clinical criteria:**

Patient must have previously been issued with an authority prescription for this drug.

**Note**

No increase in the maximum quantity or number of units may be authorised.

**Note**

No increase in the maximum number of repeats may be authorised.

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**DEXAMPHETAMINE**

*Authority required*

Use in attention deficit hyperactivity disorder, in accordance with State/Territory law

*Authority required*

Narcolepsy

**Note**

Care must be taken to comply with the provisions of State/Territory law when prescribing dexamphetamine.

**Note**
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**METHYLPHENIDATE**  
**Authority required**

Treatment of attention deficit hyperactivity disorder (ADHD) in a patient diagnosed between the ages of 6 and 18 years inclusive, who has demonstrated a response to immediate release methylphenidate hydrochloride with no emergence of serious adverse events, and who requires continuous coverage over 8 hours.

**Note**
Care must be taken to comply with the provisions of State/Territory law when prescribing methylphenidate hydrochloride.

**Note**
Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**MODAFINIL**  
**Authority required**

Initial treatment, by a qualified sleep medicine practitioner or neurologist, of patients with narcolepsy where:
(i) therapy with dexamphetamine sulfate poses an unacceptable medical risk; or
(ii) intolerance to dexamphetamine sulfate of a severity necessitating treatment withdrawal develops. The presence of any 1 of the following indicates treatment with dexamphetamine sulfate poses an unacceptable medical risk:

(a) a psychiatric disorder;
(b) a cardiovascular disorder;
(c) a history of substance abuse;
(d) glaucoma;
(e) any other absolute contraindication to dexamphetamine sulfate as specified in the TGA-approved Product Information.

Patients must meet the following definition of narcolepsy:

Excessive daytime sleepiness, recurrent naps or lapses into sleep occurring almost daily for at least 3 months and:

(i) a definite history of cataplexy;

or

a mean sleep latency less than or equal to 10 minutes on a Multiple Sleep Latency Test (MSLT). The MSLT must be preceded by nocturnal polysomnography. Sleep prior to the MSLT must be at least 6 hours in duration;

or

an electroencephalographic (EEG) recording showing the pathologically rapid development of REM sleep; and

(ii) absence of any medical or psychiatric disorder that could otherwise account for the hypersomnia.

The authority application must be made in writing and must include the following:

(a) a completed authority prescription form; and
(b) a completed Modafinil (Modavigil) PBS Authority Application for Use in the Treatment of Narcolepsy - Supporting Information Form [www.medicareaustralia.gov.au]; and
(c) details of the contraindication or intolerance to dexamphetamine sulfate; and
(d) either:
   (i) the result and date of the polysomnography test and MSLT conducted by, or under the supervision of, a qualified sleep medicine practitioner; or
   (ii) the result and date of the EEG, conducted by, or under the supervision of, a neurologist.

The polysomnography, MSLT or EEG test reports must be provided with the authority application

**Authority required**

Continuing treatment of narcolepsy, where the patient has previously been issued with an authority prescription for this drug

**Note**

Any queries concerning the arrangements to prescribe modafinil may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authority to prescribe modafinil should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Further prescribing information is on the Medicare Australia website at www.medicareaustralia.gov.au.

**Note**

Modafinil is not PBS-subsidised when used in combination with PBS-subsidised dexamphetamine sulfate.

8816B  modafinil 100 mg tablet, 60  2  5  ..  $347.32  36.90  Modavigil  CS

**ANTI-DEMENTIA DRUGS**

**Anticholinesterases**

**DONEPEZIL**

**Authority required (STREAMLINED)**

4219  Mild to moderately severe Alzheimer disease

Treatment Phase: Continuing

**Clinical criteria:**

Patient must have received six months of sole PBS-subsidised initial therapy with this drug,

AND

Patient must demonstrate a clinically meaningful response to the initial treatment,
AND

The treatment must be the sole PBS-subsidised therapy for this condition.

Prior to continuing treatment, a comprehensive assessment must be undertaken and documented, involving the patient, the patient’s family or carer and the treating physician to establish agreement that treatment is continuing to produce worthwhile benefit.

Treatment should cease if there is no agreement of benefit as there is always the possibility of harm from unnecessary use.

Re-assessments for a clinically meaningful response are to be undertaken and documented every six months.

Clinically meaningful response to treatment is demonstrated in the following areas:

Patient’s quality of life including but not limited to level of independence and happiness;

Patient’s cognitive function including but not limited to memory, recognition and interest in environment;

Patient’s behavioural symptoms, including but not limited to hallucination, delusions, anxiety, marked agitation or associated aggressive behaviour.

Note

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.
The application must be made in writing, but initial supply may be sought by telephone.

For telephone applications, up to a maximum of 2 months’ initial therapy will be authorised. This telephone application must be followed by a written authority application for no more than 1 month’s therapy and sufficient repeats to complete a maximum of up to 6 months’ initial treatment.

For written applications where no prior telephone approval has been issued, up to a maximum of 1 month’s therapy plus 5 repeats will be authorised.

**Authority required**
Mild to moderately severe Alzheimer disease

**Treatment Phase: Initial**

**Clinical criteria:**
Patient must have a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 9 or less, AND

The condition must be confirmed by, or in consultation with, a specialist/consultant physician (including a psychiatrist), AND

The treatment must be the sole PBS-subsidised therapy for this condition.

A patient who is unable to register a score of 10 or more for reasons other than their Alzheimer disease, as specified below.

Such patients will need to be assessed using the Clinicians Interview Based Impression of Severity (CIBIS) scale. The authority application must include the result of the baseline (S)MMSE and specify to which group(s) (see below) the patient belongs.

Patients who qualify under this criterion are from 1 or more of the following groups:

1. Unable to communicate adequately because of lack of competence in English, in people of non-English speaking background;
2. Limited education, as defined by less than 6 years of education, or who are illiterate or innumerate;
3. Aboriginal or Torres Strait Islanders who, by virtue of cultural factors, are unable to complete an (S)MMSE test;
4. Intellectual (developmental or acquired) disability, eg Down’s syndrome;
5. Significant sensory impairment despite best correction, which precludes completion of an (S)MMSE test;
6. Prominent dysphasia, out of proportion to other cognitive and functional impairment.

The application must be made in writing, but initial supply may be sought by telephone.

For telephone applications, up to a maximum of 2 months’ initial therapy will be authorised. This telephone application must be followed by a written authority application for no more than 1 month’s therapy and sufficient repeats to complete a maximum of up to 6 months’ initial treatment.

For written applications where no prior telephone approval has been issued, up to a maximum of 1 month’s therapy plus 5 repeats will be authorised.

**Note**
**Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

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GALANTAMINE

Authority required (STREAMLINED)

4219
Mild to moderately severe Alzheimer disease
Treatment Phase: Continuing

Clinical criteria:

Patient must have received six months of sole PBS-subsidised initial therapy with this drug,

AND

Patient must demonstrate a clinically meaningful response to the initial treatment,

AND

The treatment must be the sole PBS-subsidised therapy for this condition.

Prior to continuing treatment, a comprehensive assessment must be undertaken and documented, involving the patient, the patient's family or carer and the treating physician to establish agreement that treatment is continuing to produce worthwhile benefit.

Treatment should cease if there is no agreement of benefit as there is always the possibility of harm from unnecessary use.

Re-assessments for a clinically meaningful response are to be undertaken and documented every six months.

Clinically meaningful response to treatment is demonstrated in the following areas:

Patient’s quality of life including but not limited to level of independence and happiness;

Patient’s cognitive function including but not limited to memory, recognition and interest in environment;

Patient’s behavioural symptoms, including but not limited to hallucination, delusions, anxiety, marked agitation or associated aggressive behaviour.

Note
Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

2537M
NP
galantamine 16 mg capsule: modified release, 28 capsules
1 5 .. 56.92 36.90
a APO-Galantamine MR TX
a Galantyl AF
a Gamine XR QA
a Reminyl JC

2531F
NP
galantamine 24 mg capsule: modified release, 28 capsules
1 5 .. 66.53 36.90
a APO-Galantamine MR TX
a Galantyl AF
a Gamine XR QA
a Reminyl JC

2463P
NP
galantamine 8 mg capsule: modified release, 28 capsules
1 5 .. 48.54 36.90
a APO-Galantamine MR TX
a Galantyl AF
a Gamine XR QA
a Reminyl JC

GALANTAMINE

Authority required
Mild to moderately severe Alzheimer disease
Treatment Phase: Initial

Clinical criteria:

Patient must have a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 10 or more,

AND

The condition must be confirmed by, or in consultation with, a specialist/consultant physician (including a psychiatrist),
The treatment must be the sole PBS-subsidised therapy for this condition.

The authority application must include the result of the baseline MMSE or SMMSE. If this score is 25 - 30 points, the result of a baseline Alzheimer Disease Assessment Scale, cognitive sub-scale (ADAS-Cog) may also be specified.

The application must be made in writing, but initial supply may be sought by telephone.

For telephone applications, up to a maximum of 2 months' initial therapy will be authorised. This telephone application must be followed by a written authority application for no more than 1 month's therapy and sufficient repeats to complete a maximum of up to 6 months' initial treatment.

For written applications where no prior telephone approval has been issued, up to a maximum of 1 month's therapy plus 5 repeats will be authorised.

**Authority required**

Mild to moderately severe Alzheimer disease

**Treatment Phase: Initial**

**Clinical criteria:**

Patient must have a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 9 or less, AND

The condition must be confirmed by, or in consultation with, a specialist/consultant physician (including a psychiatrist), AND

The treatment must be the sole PBS-subsidised therapy for this condition.

A patient who is unable to register a score of 10 or more for reasons other than their Alzheimer disease, as specified below.

Patients who qualify under this criterion are from 1 or more of the following groups:

1. Unable to communicate adequately because of lack of competence in English, in people of non-English speaking background;  
2. Limited education, as defined by less than 6 years of education, or who are illiterate or innumerate;  
3. Aboriginal or Torres Strait Islanders who, by virtue of cultural factors, are unable to complete an (S)MMSE test;  
4. Intellectual (developmental or acquired) disability, eg Down's syndrome;  
5. Significant sensory impairment despite best correction, which precludes completion of an (S)MMSE test;  
6. Prominent dysphasia, out of proportion to other cognitive and functional impairment.

The application must be made in writing, but initial supply may be sought by telephone.

For telephone applications, up to a maximum of 2 months' initial therapy will be authorised. This telephone application must be followed by a written authority application for no more than 1 month's therapy and sufficient repeats to complete a maximum of up to 6 months' initial treatment.

For written applications where no prior telephone approval has been issued, up to a maximum of 1 month's therapy plus 5 repeats will be authorised.

**Note**

**Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

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<th>Dispensed Price for Max. Qty</th>
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**RIVASTIGMINE**

**Authority required (STREAMLINED)**

4219
Mild to moderately severe Alzheimer disease
Treatment Phase: Continuing

Clinical criteria:

Patient must have received six months of sole PBS-subsidised initial therapy with this drug,

AND

Patient must demonstrate a clinically meaningful response to the initial treatment,

AND

The treatment must be the sole PBS-subsidised therapy for this condition.

Prior to continuing treatment, a comprehensive assessment must be undertaken and documented, involving the patient, the patient’s family or carer and the treating physician to establish agreement that treatment is continuing to produce worthwhile benefit.

Treatment should cease if there is no agreement of benefit as there is always the possibility of harm from unnecessary use.

Re-assessments for a clinically meaningful response are to be undertaken and documented every six months.

Clinically meaningful response to treatment is demonstrated in the following areas:

Patient’s quality of life including but not limited to level of independence and happiness;

Patient’s cognitive function including but not limited to memory, recognition and interest in environment;

Patient’s behavioural symptoms, including but not limited to hallucination, delusions, anxiety, marked agitation or associated aggressive behaviour.

Note

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

RIVASTIGMINE

Authority required

Mild to moderately severe Alzheimer disease
Treatment Phase: Initial

Clinical criteria:

Patient must have a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 10 or more,

AND

The condition must be confirmed by, or in consultation with, a specialist/consultant physician (including a psychiatrist),

AND

The treatment must be the sole PBS-subsidised therapy for this condition.

The authority application must include the result of the baseline MMSE or SMMSE. If this score is 25 - 30 points, the result of a baseline Alzheimer Disease Assessment Scale, cognitive sub-scale (ADAS-Cog) may also be specified.

The application must be made in writing, but initial supply may be sought by telephone.

For telephone applications, up to a maximum of 2 months' initial therapy will be authorised. This telephone application must be followed by a written authority application for no more than 1 month's therapy and sufficient repeats to complete a maximum of up to 6 months' initial treatment.

For written applications where no prior telephone approval has been issued, up to a maximum of 1 month's therapy plus 5 repeats will be authorised.

Authority required

Mild to moderately severe Alzheimer disease
Treatment Phase: Initial

Clinical criteria:
NERVOUS SYSTEM

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<td>Exelon</td>
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<td>Exelon Patch 10</td>
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</table>

**Other anti-dementia drugs**

**MEMANTINE**

**Authority required**

Moderately severe Alzheimer disease

**Treatment Phase:** Initial

**Clinical criteria:**

Patient must have a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 10 to 14, AND

The condition must be confirmed by, or in consultation with, a specialist/consultant physician (including a psychiatrist), AND

The treatment must be the sole PBS-subsidised therapy for this condition.

The authority application must include the result of the baseline MMSE or SMMSE of 10 to 14.

The application must be made in writing, but initial supply may be sought by telephone.

For telephone applications, up to a maximum of 2 months' initial therapy will be authorised. This telephone application must be followed by a written authority application for no more than 1 month's therapy and sufficient repeats to complete a maximum of up to 6 months' initial treatment.

For written applications where no prior telephone approval has been issued, up to a maximum of 1 month's therapy plus 5 repeats will be authorised.

**Note**

**Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.
Moderately severe Alzheimer disease

Treatment Phase: Initial

Clinical criteria:

Patient must have a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 9 or less, AND the condition must be confirmed by, or in consultation with, a specialist/consultant physician (including a psychiatrist), AND the treatment must be the sole PBS-subsidised therapy for this condition.

Patients who qualify under this criterion are from 1 or more of the following groups:

1. Unable to communicate adequately because of lack of competence in English, in people of non-English speaking background;
2. Limited education, as defined by less than 6 years of education, or who are illiterate or innumerate;
3. Aboriginal or Torres Strait Islanders who, by virtue of cultural factors, are unable to complete an (S)MMSE test;
4. Intellectual (developmental or acquired) disability, eg Down's syndrome;
5. Significant sensory impairment despite best correction, which precludes completion of an (S)MMSE test;
6. Prominent dysphasia, out of proportion to other cognitive and functional impairment.

The application must be made in writing, but initial supply may be sought by telephone.

For telephone applications, up to a maximum of 2 months' initial therapy will be authorised. This telephone application must be followed by a written authority application for no more than 1 month's therapy and sufficient repeats to complete a maximum of up to 6 months' initial treatment.

For written applications where no prior telephone approval has been issued, up to a maximum of 1 month's therapy plus 5 repeats will be authorised.

Note

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

### MEMANTINE

Authority required (STREAMLINED)

4214

Moderately severe Alzheimer disease

Treatment Phase: Continuing

Clinical criteria:

Patient must have received six months of sole PBS-subsidised initial therapy with this drug, AND patient must demonstrate a clinically meaningful response to the initial treatment, AND the treatment must be the sole PBS-subsidised therapy for this condition.

Prior to continuing treatment, a comprehensive assessment must be undertaken and documented, involving the patient, the patient's family or carer and the treating physician to establish agreement that treatment is continuing to produce worthwhile benefit. Treatment should cease if there is no agreement of benefit as there is always the possibility of harm from unnecessary use.

Re-assessments for a clinically meaningful response are to be undertaken and documented every six months. Clinically meaningful response to treatment is demonstrated in the following areas:

Patient's quality of life including but not limited to level of independence and happiness;
Patient’s cognitive function including but not limited to memory, recognition and interest in environment;
Patient’s behavioural symptoms, including but not limited to hallucination, delusions, anxiety, marked agitation or associated aggressive behaviour.

**Note**

*Continuing Therapy Only:*

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

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**OTHER NERVOUS SYSTEM DRUGS**

**PARASYMPATHOMIMETICS**

**Anticholinesterases**

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**Choline esters**

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**DRUGS USED IN ADDICTIVE DISORDERS**

**BUPROPION**

**Authority required**

Commencement of short-term, sole PBS-subsidised, therapy as an aid to achieving abstinence in a patient who has previously been issued with an authority prescription for this drug and who is enrolled in a comprehensive support and counselling program.

**Note**

Only one course of PBS-subsidised bupropion hydrochloride will be authorised per 12 months. The period between commencing a course of bupropion hydrochloride and varenicline tartrate must be at least 6 months. A course of treatment with bupropion hydrochloride is 9 weeks. No increased maximum quantities or repeats will be authorised. Clinical review is recommended within 2 to 3 weeks of the original prescription being requested.

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**BUPROPION**

**Authority required**

Completion of short-term, sole PBS-subsidised, therapy as an aid to achieving abstinence in a patient who has previously been issued with an authority prescription for this drug and who is enrolled in a comprehensive support and counselling program.

**Note**

Only one course of PBS-subsidised bupropion hydrochloride will be authorised per 12 months. The period between commencing a course of bupropion hydrochloride and varenicline tartrate must be at least 6 months. A course of treatment with bupropion hydrochloride is 9 weeks. No increased maximum quantities or repeats will be authorised. Clinical review is recommended within 2 to 3 weeks of the original prescription being requested.
### NERVOUS SYSTEM

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<td>Nicotine dependence</td>
<td>Clinical criteria:</td>
<td>The treatment must be the sole PBS-subsidised therapy for this condition,</td>
<td>AND</td>
<td>Patient must have indicated they are ready to cease smoking,</td>
<td>AND</td>
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<td>Nicotine dependence</td>
<td>Clinical criteria:</td>
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### Note

No increase in the maximum quantity or number of units may be authorised.

No increase in the maximum number of repeats may be authorised.

### Authority required (STREAMLINED)

4344

Nicotine dependence

Clinical criteria:
The treatment must be the sole PBS-subsidised therapy for this condition.

Population criteria:
Patient must be an Aboriginal or a Torres Strait Islander person.

Note

Only 2 courses of PBS-subsidised nicotine replacement therapy may be prescribed per 12-month period.

Benefit is improved if used in conjunction with a comprehensive support and counselling program.

Note

No increase in the maximum quantity or number of units may be authorised.

Note

No increase in the maximum number of repeats may be authorised.
The treatment must be the sole PBS-subsidised therapy for this condition, AND

Patient must have indicated they are ready to cease smoking, AND

Patient must have entered a comprehensive support and counselling program, AND

Patient must not receive more than 12 weeks of PBS-subsidised nicotine replacement therapy per 12-month period.

Details of the support and counselling program must be documented in the patient’s medical records at the time treatment is initiated.

Note
No increase in the maximum quantity or number of units may be authorised.

Note
No increase in the maximum number of repeats may be authorised.

**Authority required (STREAMLINED)**

4307

Nicotine dependence

**Clinical criteria:**

The treatment must be the sole PBS-subsidised therapy for this condition, AND

Patient must have indicated they are ready to cease smoking, AND

Patient must be entering a comprehensive support and counselling program during the consultation at which this prescription is written, AND

Patient must not receive more than 12 weeks of PBS-subsidised nicotine replacement therapy per 12-month period.

Details of the support and counselling program must be documented in the patient’s medical records at the time treatment is initiated.

Note
No increase in the maximum quantity or number of units may be authorised.

Note
No increase in the maximum number of repeats may be authorised.

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**NICOTINE**

**Authority required (STREAMLINED)**

4344

Nicotine dependence

**Clinical criteria:**

The treatment must be the sole PBS-subsidised therapy for this condition.

**Population criteria:**

Patient must be an Aboriginal or a Torres Strait Islander person.

Note
Only 2 courses of PBS-subsidised nicotine replacement therapy may be prescribed per 12-month period.

Benefit is improved if used in conjunction with a comprehensive support and counselling program.

Note
No increase in the maximum quantity or number of units may be authorised.

Note
No increase in the maximum number of repeats may be authorised.

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<td>Nicotinell Step 1</td>
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**VARENICLINE**

**Authority required**

Completion of short-term sole PBS-subsidised therapy as an aid to achieving long-term abstinence after completion of an initial 12-week PBS-subsidised course in a patient who has ceased smoking, and who is enrolled in a comprehensive support and counselling program

Note
A course of treatment with varenicline tartrate is 12 weeks or up to 24 weeks, if initial treatment of 12 weeks has been successful. Only one course of 12 or up to 24 weeks of PBS-subsidised varenicline tartrate will be authorised per year. The period between commencing varenicline tartrate and bupropion hydrochloride must be at least 6 months. No increased maximum quantities or repeats will be authorised. Clinical review is recommended within 2 to 3 weeks of the initial prescription being requested.

**VARENICLINE**

**Authority required**

Continuation of short-term sole PBS-subsidised therapy as an aid to achieving abstinence in a patient who has previously been issued with an authority prescription for this drug and who is enrolled in a comprehensive support and counselling program.

**Note**

A course of treatment with varenicline tartrate is 12 weeks or up to 24 weeks, if initial treatment of 12 weeks has been successful. Only one course of 12 or up to 24 weeks of PBS-subsidised varenicline tartrate will be authorised per year. The period between commencing varenicline tartrate and bupropion hydrochloride must be at least 6 months. No increased maximum quantities or repeats will be authorised. Clinical review is recommended within 2 to 3 weeks of the initial prescription being requested.

**Drugs used in alcohol dependence**

**ACAMPROSATE**

**Authority required (STREAMLINED)**

For use within a comprehensive treatment program for alcohol dependence with the goal of maintaining abstinence.

**Note**

No applications for increased maximum quantities and/or repeats will be authorised.

**NALTREXONE**

**Authority required**

For use within a comprehensive treatment program for alcohol dependence with the goal of maintaining abstinence.

**Caution**

Naltrexone hydrochloride is contraindicated in patients receiving opioid drugs.

**Note**

No applications for increased maximum quantities and/or repeats will be authorised.

**OTHER NERVOUS SYSTEM DRUGS**

**Other nervous system drugs**

**DIMETHYL FUMARATE**

**Authority required**

Multiple sclerosis.
Treatment Phase: Initial treatment

Clinical criteria:

The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR

The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient, AND

The treatment must be as monotherapy, AND

Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to the multiple sclerosis, in the preceding 2 years, AND

Patient must be ambulatory (without assistance or support).

Where applicable, the date of the magnetic resonance imaging scan must be provided with the authority application.

Note
No increase in the maximum quantity or number of units may be authorised.

Note
No increase in the maximum number of repeats may be authorised.

Note
Special Pricing Arrangements apply.

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DIMETHYL FUMARATE
Authority required
Multiple sclerosis
Treatment Phase: Continuing treatment

Clinical criteria:

The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR

The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient, AND

The treatment must be as monotherapy, AND

Patient must have previously been issued with an authority prescription for this drug; OR

Patient must have been receiving treatment with this drug prior to 1 December 2013, AND

Patient must not show continuing progression of disability while on treatment with this drug.

Where applicable, the date of the magnetic resonance imaging scan must be provided with the authority application.

Note
Special Pricing Arrangements apply.

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**NERVOUS SYSTEM**

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**RILUZOLE**

**Authority required**

Initial treatment of amyotrophic lateral sclerosis, as diagnosed by a neurologist, in patients with disease duration of 5 years or less and who have at least 60 percent of predicted forced vital capacity within 2 months prior to commencing riluzole therapy and who:

1. are ambulatory, and
   1a. have not undergone tracheostomy, and
   1b. have not experienced respiratory failure; OR
   2. are not ambulatory, and
   2a. have not undergone tracheostomy, and
   2b. have not experienced respiratory failure, and
   2c. are either able to use upper limbs or able to swallow.

The date of diagnosis and the date and results of spirometry (in terms of percent of predicted forced vital capacity) must be supplied with the initial authority application.

**Authority required**

Continuing treatment of amyotrophic lateral sclerosis in patients who have previously been issued with an authority prescription for this drug and who:

1. are ambulatory, and
   1a. have not undergone tracheostomy, and
   1b. have not experienced respiratory failure; OR
   2. are not ambulatory, and
   2a. have not undergone tracheostomy, and
   2b. have not experienced respiratory failure, and
   2c. are either able to use upper limbs or able to swallow.

**Note**

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**TETRABENAZINE**

**Authority required (STREAMLINED)**

Hyperkinetic extrapyramidal disorders

**Note**

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.
<table>
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IA
### Antiparasitic Products, Insecticides and Repellents

**Antiprotozoals**

- **Agents Against Amoebiasis and Other Protozoal Diseases**
  - *Other agents against amoebiasis and other protozoal diseases*

  **Atovaquone**
  - Authority required (STREAMLINED)
  - 1433
  - Treatment of mild to moderate Pneumocystis carinii pneumonia in adult patients who are intolerant of trimethoprim/sulfamethoxazole therapy

  **Note**
  - Shared Care Model:
  - For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

  **Pyrimethamine**
  - 1966L
  - Pyrimethamine 25 mg tablet, 50

### Antimalarials

- **Biguanides**

  **Atovaquone + Proguanil**
  - Authority required
  - Treatment of suspected or confirmed Plasmodium falciparum malaria in a patient aged 3 years or older where quinine containing regimens are inappropriate

  **Note**
  - Atovaquone with proguanil hydrochloride is not PBS-subsidised for the prophylaxis of malaria.

  **Note**
  - Shared Care Model:
  - For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

### Methanolquinolines

- **Quinine**
  - Authority required (STREAMLINED)
  - 2142
  - Malaria
  - Caution
  - Severe thrombocytopenia has been reported with this drug.

  **Note**
  - Severe thrombocytopenia has been reported with this drug.

  **Artemisinin and derivatives, combinations**

  **Artemether + Lumefantrine**
  - Authority required
  - Treatment of suspected or confirmed malaria due to Plasmodium falciparum

  **Note**
  - Artemether with lumefantrine is not PBS-subsidised for prophylaxis of malaria.

  **Note**
  - Artemether with lumefantrine is not PBS-subsidised for prophylaxis of malaria.

  **Artemether + Lumefantrine**
  - Authority required
  - Treatment of suspected or confirmed malaria due to Plasmodium falciparum in a patient unable to swallow a solid dosage form of artemether with
ANTIPARASITIC PRODUCTS, INSECTICIDES AND REPELLENTS

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**Note**
Artemether with lumefantrine is not PBS-subsidised for prophylaxis of malaria.

ANTHELMINTICS

**ANTITREMATODALS**

*Quinoline derivatives and related substances*

**PRAZIQUANTEL**  
Authority required (STREAMLINED)  
3147  
Schistosomiasis

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**ANTINEMATODAL AGENTS**

*Benzimidazole derivatives*

**ALBENDAZOLE**  
Authority required (STREAMLINED)  
1525  
Treatment of tapeworm infestation

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<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>8503M</td>
<td>albendazole 200 mg tablet: chewable, 6</td>
<td>1</td>
<td>1</td>
<td>..</td>
<td>33.44</td>
<td>34.59</td>
<td>Zentel</td>
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</table>

**ALBENDAZOLE**  
Authority required (STREAMLINED)  
2446  
Treatment of whipworm infestation in an Aboriginal or a Torres Strait Islander person

**Authority required (STREAMLINED)**  
1388  
Strongyloidiasis

**Authority required (STREAMLINED)**  
3241  
Treatment of hookworm infestation

<table>
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<tr>
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<td>9047E</td>
<td>albendazole 200 mg tablet: chewable, 6</td>
<td>1</td>
<td>..</td>
<td>..</td>
<td>33.44</td>
<td>34.59</td>
<td>Zentel</td>
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**ALBENDAZOLE**  
Authority required (STREAMLINED)  
1496  
For the treatment of hydatid disease in conjunction with surgery or when a surgical cure cannot be achieved or where surgery cannot be used

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<th>Name, Restriction, Manner of Administration and Form</th>
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<tr>
<td>8459F</td>
<td>albendazole 400 mg tablet: chewable, 60</td>
<td>1</td>
<td>2</td>
<td>..</td>
<td>185.59</td>
<td>36.90</td>
<td>Eskazole</td>
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</table>

**Tetrahydropyrimidine derivatives**

**PYRANTEL**  
3047J  
pyrantel 125 mg tablet, 6

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<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Pack(s))</th>
<th>No. of Rpts</th>
<th>Premium $</th>
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<th>Brand Name and Manufacturer</th>
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<tr>
<td>3047J</td>
<td>pyrantel 125 mg tablet, 6</td>
<td>1</td>
<td>..</td>
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<td>14.94</td>
<td>16.09</td>
<td>Anthel 125</td>
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</table>

**PYRANTEL**  
3048K  
pyrantel 250 mg tablet, 6

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<th>Max. Qty (Pack(s))</th>
<th>No. of Rpts</th>
<th>Premium $</th>
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<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
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<tr>
<td>3048K</td>
<td>pyrantel 250 mg tablet, 6</td>
<td>1</td>
<td>..</td>
<td>..</td>
<td>23.11</td>
<td>24.26</td>
<td>Anthel 250</td>
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**Avermectines**

**IVERMECTIN**  
Authority required (STREAMLINED)  
4328  
Strongyloidiasis

**Authority required (STREAMLINED)**  
4565  
Crusted (Norwegian) scabies

Clinical criteria:
The condition must be established by clinical and/or parasitological examination,
AND
Patient must be undergoing topical therapy for this condition; OR
Patient must have a contraindication to topical treatment.

**Population criteria:**
Patient must weigh 15 kg or over,
AND
Patient must be 5 years of age or older.

**Authority required (STREAMLINED)**

**4566**
Human sarcoptic scabies

**Clinical criteria:**
The condition must be established by clinical and/or parasitological examination,
AND
Patient must have completed and failed sequential treatment with topical permethrin and benzyl benzoate and finished the most recent course of topical therapy at least 4 weeks prior to initiating oral therapy; OR
Patient must have a contraindication to topical treatment.

**Population criteria:**
Patient must weigh 15 kg or over,
AND
Patient must be 5 years of age or older.

**Note**
This drug is not PBS-subsidised for first line treatment of typical scabies.

<table>
<thead>
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<th>Name, Restriction, Manner of Administration and Form</th>
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<td>2868Y NP</td>
<td>ivermectin 3 mg tablet, 4</td>
<td>2</td>
<td>2</td>
<td>..</td>
<td>*54.54</td>
<td>36.90</td>
<td>Stromectol MK</td>
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</table>

**IVERMECTIN**

**Authority required (STREAMLINED)**

**4319**
Onchocerciasis

<table>
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<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>8359Y NP</td>
<td>ivermectin 3 mg tablet, 4</td>
<td>1</td>
<td>..</td>
<td>..</td>
<td>31.65</td>
<td>32.80</td>
<td>Stromectol MK</td>
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</tbody>
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**ECTOPARASITICIDES, INCL. SCABICIDES, INSECTICIDES AND REPELLENTS**

**ECTOPARASITICIDES, INCL. SCABICIDES**

*Pyrethrines, incl. synthetic compounds*

**PERMETHRIN**

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
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<th>Premium $</th>
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<th>Brand Name and Manufacturer</th>
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<tr>
<td>3054R NP</td>
<td>permethrin 5% cream, 30 g</td>
<td>‡1</td>
<td>1</td>
<td>..</td>
<td>17.11</td>
<td>18.26</td>
<td>Lyclear JT</td>
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</table>
### RESPIRATORY SYSTEM

#### NASAL PREPARATIONS

**DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE**

**Other nasal preparations**

**MUPIROCIN**

**Authority required [STREAMLINED]**

3136

Nasal colonisation with Staphylococcus aureus in an Aboriginal or a Torres Strait Islander person

**Note**

No applications for increased maximum quantities and/or repeats will be authorised.

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
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<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>9440W</td>
<td>mupirocin 2% (20 mg/g) ointment, 3 g ‡1 .. ..</td>
<td>1</td>
<td>5</td>
<td>..</td>
<td>20.97</td>
<td>22.12</td>
<td>Bactroban</td>
</tr>
</tbody>
</table>

#### DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES

**ADRENERGICS, INHALANTS**

**Selective beta-2-adrenoreceptor agonists**

**EFOMOTEROL**

**Restricted benefit**

Patients with frequent episodes of asthma who are currently receiving treatment with oral corticosteroids

**Restricted benefit**

Patients with frequent episodes of asthma who are currently receiving treatment with optimal doses of inhaled corticosteroids

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
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<th>No. of Rpts</th>
<th>Dispensed Price for Max. Qty $</th>
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<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>8136F</td>
<td>eformoterol fumarate dihydrate 12 microgram inhalation: powder for, 60 capsules</td>
<td>1</td>
<td>5</td>
<td>..</td>
<td>37.67</td>
<td>36.90</td>
<td>Foradile</td>
</tr>
<tr>
<td>8240Q</td>
<td>eformoterol fumarate dihydrate 12 microgram/actuation inhalation: powder for, 60 actuations</td>
<td>‡1</td>
<td>5</td>
<td>..</td>
<td>36.78</td>
<td>36.90</td>
<td>Oxis Turbuhaler</td>
</tr>
<tr>
<td>8239P</td>
<td>eformoterol fumarate dihydrate 6 microgram/actuation inhalation: powder for, 60 actuations</td>
<td>‡1</td>
<td>5</td>
<td>..</td>
<td>26.72</td>
<td>27.87</td>
<td>Oxis Turbuhaler</td>
</tr>
</tbody>
</table>

**INDACATEROL**

**Restricted benefit**

Chronic obstructive pulmonary disease

**Note**

Indacaterol is not PBS-subsidised for the treatment of asthma.

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
<th>Dispensed Price for Max. Qty $</th>
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<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>5134F</td>
<td>indacaterol 150 microgram inhalation: powder for, 60 capsules</td>
<td>1</td>
<td>5</td>
<td>..</td>
<td>73.78</td>
<td>36.90</td>
<td>Onbrez</td>
</tr>
<tr>
<td>5137J</td>
<td>indacaterol 300 microgram inhalation: powder for, 60 capsules</td>
<td>1</td>
<td>5</td>
<td>..</td>
<td>73.78</td>
<td>36.90</td>
<td>Onbrez</td>
</tr>
</tbody>
</table>

**SALBUTAMOL**

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
<th>Dispensed Price for Max. Qty $</th>
<th>Premium $</th>
<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>8288F</td>
<td>salbutamol 100 microgram/actuation inhalation: pressurised, 200</td>
<td>2</td>
<td>5</td>
<td>..</td>
<td>*14.14</td>
<td>15.29</td>
<td>3.4</td>
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<tr>
<td>1099W</td>
<td>salbutamol 200 microgram inhalation: powder for, 100 capsules</td>
<td>2</td>
<td>5</td>
<td>..</td>
<td>*16.40</td>
<td>17.55</td>
<td>Ventolin Rotacaps</td>
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</tbody>
</table>

**SALBUTAMOL**

**Restricted benefit**

Asthma in patients unable to use this drug delivered from an oral pressurised inhalation device via a spacer

**Restricted benefit**

Chronic obstructive pulmonary disease in patients unable to use this drug delivered from an oral pressurised inhalation device via a spacer

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
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<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>2000G</td>
<td>salbutamol 2.5 mg/2.5 mL inhalation: solution, 30 x 2.5 mL ampoules</td>
<td>2</td>
<td>5</td>
<td>..</td>
<td>*15.96</td>
<td>17.11</td>
<td>APO-Salbutamol</td>
</tr>
<tr>
<td></td>
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<td></td>
<td>APO-Salbutamol</td>
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<td>Asmol 2.5 uni-dose</td>
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### RESPIRATORY SYSTEM

<table>
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<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
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<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>2001H</td>
<td>salbutamol 5 mg/2.5 mL inhalation: solution, 30 x 2.5 mL ampoules</td>
<td>2 5</td>
<td>..</td>
<td></td>
<td>8 1.20</td>
<td>*17.16</td>
<td>17.11</td>
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<tr>
<td>8354Q</td>
<td>salbutamol Oral pressurised inhalation in breath actuated device 100 micrograms (base) per dose (200 doses), CFC-free formulation,</td>
<td>2 5</td>
<td>..</td>
<td></td>
<td>8 1.16</td>
<td>*17.60</td>
<td>17.59</td>
</tr>
<tr>
<td>NP</td>
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<td></td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>8141L</td>
<td>salmeterol 50 microgram/actuation inhalation: powder for, 60 actuations</td>
<td>‡1 5</td>
<td>..</td>
<td></td>
<td>37.67</td>
<td>36.90</td>
<td>Serevent Accuhaler GK</td>
</tr>
<tr>
<td>NP</td>
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</tr>
<tr>
<td>2817G</td>
<td>terbutaline sulfate 500 microgram/actuation inhalation: powder for, 100 actuations</td>
<td>2 5</td>
<td>..</td>
<td></td>
<td>18.20</td>
<td>19.35</td>
<td>Bricanyl Turbuhaler AP</td>
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<td>NP</td>
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</tbody>
</table>

**SALBUTAMOL**

**Restricted benefit**

Patients unable to achieve co-ordinated use of other metered dose inhalers containing this drug

**SALMETEROL**

**Restricted benefit**

Patients with frequent episodes of asthma who are currently receiving treatment with oral corticosteroids

**TERBUTALINE**

**Adrenergics and other drugs for obstructive airway diseases**

**BUDESONIDE + EFORMOTEROL**

**Restricted benefit**

Asthma

**Clinical criteria:**

Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids; OR

Patient must have experienced frequent asthma symptoms while receiving treatment with oral or inhaled corticosteroids and require single maintenance and reliever therapy; OR

Patient must have experienced frequent asthma symptoms while receiving treatment with a combination of an inhaled corticosteroid and long acting beta-2 agonist.

**Population criteria:**

Patient must be aged 12 years or over.

**10015D**

budesonide 100 microgram/actuation + eformoterol fumarate dihydrate 3 microgram/actuation inhalation: pressurised, 120 actuations

**10024N**

budesonide 50 microgram/actuation + eformoterol fumarate dihydrate 3 microgram/actuation inhalation: pressurised, 120 actuations

**BUDESONIDE + EFORMOTEROL**

**Restricted benefit**

Asthma
<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
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<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>8796Y</td>
<td>Budesonide 100 microgram/actuation + eformoterol fumarate dihydrate 6 microgram/actuation inhalation: powder for, 120 actuations</td>
<td>‡1</td>
<td>5</td>
<td>54.81</td>
<td>36.90</td>
<td>Symbicort Turbuhaler 100/6</td>
<td>AP</td>
</tr>
<tr>
<td>8625Y</td>
<td>Budesonide 200 microgram/actuation + eformoterol fumarate dihydrate 6 microgram/actuation inhalation: powder for, 120 actuations</td>
<td>‡1</td>
<td>5</td>
<td>59.11</td>
<td>36.90</td>
<td>Symbicort Turbuhaler 200/6</td>
<td>AP</td>
</tr>
</tbody>
</table>

**BUDESONIDE + EFORMOTEROL**

**Restricted benefit**

**Asthma**

**Clinical criteria:**

Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids.

**Population criteria:**

Patient must be aged 12 years or over.

**Note**

Unlike Symbicort Turbuhaler 200/6, Symbicort Rapihaler 200/6 is not recommended nor PBS-subsidised for use as ‘maintenance and reliever’ therapy as the approved Product Information does not specify such use.

**Restricted benefit**

**Chronic obstructive pulmonary disease (COPD)**

**Clinical criteria:**

Patient must have a forced expiratory volume in 1 second (FEV1) less than 50% of predicted normal prior to therapy, AND

**Note**

Budesonide with eformoterol fumarate dihydrate is not indicated for the initiation of bronchodilator therapy in COPD.

**BUDESONIDE + EFORMOTEROL**

**Restricted benefit**

**Asthma**

**Clinical criteria:**

Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids.

**Population criteria:**

Patient must be aged 12 years or over.

**Note**

Symbicort 400/12 is not recommended nor PBS-subsidised for use as ‘maintenance and reliever’ therapy.

**Restricted benefit**

**Chronic obstructive pulmonary disease (COPD)**

**Clinical criteria:**

Patient must have a forced expiratory volume in 1 second (FEV1) less than 50% of predicted normal prior to therapy, AND

**Note**

Symbicort 400/12 is not recommended nor PBS-subsidised for use as ‘maintenance and reliever’ therapy.
<table>
<thead>
<tr>
<th>Code</th>
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<th>Premium $</th>
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<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>8750M</td>
<td>budesonide 400 microgram/actuation + eformoterol fumarate dihydrate 12 microgram/actuation inhalation: powder for, 120 actuations</td>
<td>‡1 5 ..</td>
<td>90.89</td>
<td>36.90</td>
<td>Symbicort Turbuhaler 400/12</td>
<td></td>
<td>AP</td>
</tr>
<tr>
<td>10007Q</td>
<td>fluticasone propionate 125 microgram/actuation + eformoterol fumarate dihydrate 5 microgram/actuation inhalation: pressurised, 120 actuations</td>
<td>‡1 5 ..</td>
<td>56.71</td>
<td>36.90</td>
<td>flutiform 125/5</td>
<td></td>
<td>MF</td>
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<td>flutiform 250/10</td>
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<td>Seretide Accuhaler 100/50</td>
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<td>fluticasone propionate 125 microgram/actuation + salmeterol 25 microgram/actuation inhalation: pressurised, 120 actuations</td>
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<td>Seretide Accuhaler 250/50</td>
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<td>8517G</td>
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<td>47.54</td>
<td>36.90</td>
<td>Seretide MDI 50/25</td>
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<td>GK</td>
</tr>
</tbody>
</table>

**FLUTICASONE + EFORMOTEROL**

**Restricted benefit**

**Asthma**

**Clinical criteria:**

Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids.

**Population criteria:**

Patient must be aged 12 years or over.

**Note**

Budesonide with eformoterol fumarate dihydrate is not indicated for the initiation of bronchodilator therapy in COPD.

**Note**

Flutiform is not recommended nor PBS-subsidised for use as ‘maintenance and reliever’ therapy.

**Note**

Flutiform is not indicated or PBS-subsidised for bronchodilator therapy in COPD.

**FLUTICASONE + SALMETEROL**

**Restricted benefit**

**Asthma**

**Clinical criteria:**

Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids.

**AND**

Patient must have been stabilised on concomitant inhaled salmeterol xinafoate and fluticasone propionate if aged less than 12 years.

**Note**

The treatment must be for symptomatic treatment.
## RESPIRATORY SYSTEM

### Asthma

**Clinical criteria:**

Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids,

**AND**

Patient must have been stabilised on concomitant inhaled salmeterol xinafoate and fluticasone propionate if aged less than 12 years.

**Restricted benefit**

Chronic obstructive pulmonary disease (COPD)

**Clinical criteria:**

Patient must have a forced expiratory volume in 1 second (FEV1) less than 50% of predicted normal prior to therapy,

**AND**

Patient must have a history of repeated exacerbations with significant symptoms despite regular beta-2 agonist bronchodilator therapy,

**AND**

The treatment must be for symptomatic treatment.

**Note**

Seretide is not indicated for the initiation of bronchodilator therapy in COPD.

### OTHER DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, INHALANTS

#### Glucocorticoids

**BECLOMETHASONE**

**Restricted benefit**

Patients unable to achieve co-ordinated use of other metered dose inhalers containing this drug

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
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<td>36.90</td>
<td>Seretide MDI 250/25</td>
<td>GK</td>
<td></td>
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<tr>
<td>8432T</td>
<td>fluticasone propionate 500 microgram/actuation + salmeterol 50 microgram/actuation inhalation: powder for, 60 actuations</td>
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<td>78.78</td>
<td>36.90</td>
<td>Seretide Accuhaler 500/50</td>
<td>GK</td>
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#### BECLOMETHASONE DIPROPIONATE

**Authority required (STREAMLINED)**

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<th>Code</th>
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<td>8409N</td>
<td>Oral pressurised inhalation in breath actuated device 100 micrograms per dose (200 doses), CFC-free formulation, 1</td>
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<td>39.47</td>
<td>36.90</td>
<td>Qvar 100 Autohaler</td>
<td>IA</td>
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<td>8408M</td>
<td>Oral pressurised inhalation in breath actuated device 50 micrograms per dose (200 doses), CFC-free formulation, 1</td>
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<td>28.21</td>
<td>29.36</td>
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#### BECLOMETHASONE DIPROPIONATE

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<td>8407L</td>
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<td>Qvar 50</td>
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#### BUDESONIDE

**Authority required (STREAMLINED)**

Severe chronic asthma in patients who require long-term steroid therapy and who are unable to use other forms of inhaled steroid therapy

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<tr>
<td>2066R</td>
<td>budesonide 1 mg/2 mL inhalation: solution, 30 x 2 mL ampoules</td>
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<td>49.34</td>
<td>36.90</td>
<td>Pulmicort Respules</td>
<td>AP</td>
<td></td>
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<tr>
<td>2065Q</td>
<td>budesonide 500 microgram/2 mL inhalation: solution, 30 x 2 mL ampoules</td>
<td>‡1 5 ..</td>
<td>38.20</td>
<td>36.90</td>
<td>Pulmicort Respules</td>
<td>AP</td>
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#### BUDESONIDE

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<td>budesonide 100 microgram/actuation</td>
<td>‡1 5 ..</td>
<td>23.68</td>
<td>24.83</td>
<td>Pulmicort Turbuhaler</td>
<td>AP</td>
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<td>Code</td>
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<tr>
<td>NP</td>
<td>inhalation: powder for, 200 actuations</td>
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<td>31.42</td>
<td>32.57</td>
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<tr>
<td>2071B</td>
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<td>46.18</td>
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<td>42.59</td>
<td>36.90</td>
<td>Alvesco 160 NQ</td>
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<td>26.49</td>
<td>27.64</td>
<td>Alvesco 80 NQ</td>
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<td>fluticasone propionate 100 microgram/actuation inhalation: powder for, 60 actuations</td>
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<td>5</td>
<td>..</td>
<td>17.43</td>
<td>18.58</td>
<td>Flixotide Junior Accuhaler GK</td>
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<tr>
<td>8147T</td>
<td>fluticasone propionate 125 microgram/actuation inhalation: pressurised, 120 actuations</td>
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<td>5</td>
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<td>31.00</td>
<td>32.15</td>
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<tr>
<td>NP</td>
<td>fluticasone propionate 250 microgram/actuation inhalation: powder for, 60 actuations</td>
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<td>5</td>
<td>..</td>
<td>31.00</td>
<td>32.15</td>
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<tr>
<td>8346G</td>
<td>fluticasone propionate 250 microgram/actuation inhalation: pressurised, 120 actuations</td>
<td>‡1</td>
<td>1</td>
<td>..</td>
<td>50.06</td>
<td>36.90</td>
<td>Flixotide Accuhaler GK</td>
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<tr>
<td>NP</td>
<td>fluticasone propionate 50 microgram/actuation inhalation: pressurised, 120 actuations</td>
<td>‡1</td>
<td>5</td>
<td>..</td>
<td>17.43</td>
<td>18.58</td>
<td>Flixotide Junior Accuhaler GK</td>
</tr>
<tr>
<td>8149X</td>
<td>fluticasone propionate 500 microgram/actuation inhalation: powder for, 60 actuations</td>
<td>‡1</td>
<td>1</td>
<td>..</td>
<td>50.06</td>
<td>36.90</td>
<td>Flixotide Accuhaler GK</td>
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</table>

**Anticholinergics**

**ACLIDINIUM**

**Restricted benefit**

Chronic obstructive pulmonary disease (COPD)

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
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<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>NP</td>
<td>aclidinium bromide 400 microgram/actuation inhalation: powder for, 60 actuations</td>
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<td>..</td>
<td>62.73</td>
<td>36.90</td>
<td>Bretaris Genuair FK</td>
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**GLYCOPYRRONIUM**

**Restricted benefit**

Chronic obstructive pulmonary disease (COPD)

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<td>NP</td>
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<td>5</td>
<td>..</td>
<td>73.78</td>
<td>36.90</td>
<td>seebri breezhaler NV</td>
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**IPRATROPION**

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<td>NP</td>
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<td>5</td>
<td>..</td>
<td>*34.18</td>
<td>35.33</td>
<td>Atravent BY</td>
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**IPRATROPION**

**Restricted benefit**

Asthma in patients unable to use this drug delivered from an oral pressurised inhalation device via a spacer

**Restricted benefit**

Chronic obstructive pulmonary disease in patients unable to use this drug delivered from an oral pressurised inhalation device via a spacer

<table>
<thead>
<tr>
<th>Code</th>
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<td>NP</td>
<td>ipratropium bromide 250 microgram/mL inhalation: solution, 30 x 1 mL ampoules</td>
<td>2</td>
<td>5</td>
<td>..</td>
<td>*28.28</td>
<td>29.43</td>
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<td>1542E</td>
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<td>5</td>
<td>..</td>
<td>*28.80</td>
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RESPIRATORY SYSTEM

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<td>Tiotropium Restricted benefit</td>
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<td>Spiriva BY</td>
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<td>Antiallergic agents, excl. corticosteroids</td>
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<td>33.84</td>
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<td>36.90</td>
<td>Intal Forte CFC-Free SW</td>
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<td>Alpha- and beta-adrenoreceptor agonists</td>
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<td>1016L</td>
<td>adrenaline 1 in 1000 (1 mg/mL) injection, 5 x 1 mL ampoules</td>
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<td>20.68</td>
<td>21.83</td>
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<td>Alpha- and beta-adrenoreceptor agonists</td>
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<td>3408J</td>
<td>adrenaline 150 microgram/0.3 mL injection, 1 x 0.3 mL syringe</td>
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<td>36.90</td>
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<td>106.34</td>
<td>36.90</td>
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<td>106.34</td>
<td>36.90</td>
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<td>8698T</td>
<td>adrenaline 300 microgram/0.3 mL injection, 1 x 0.3 mL syringe</td>
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<td></td>
<td>106.34</td>
<td>36.90</td>
<td>EpiPen AL</td>
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Selective beta-2-adrenoreceptor agonists

SALBUTAMOL
### RESPIRATORY SYSTEM

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<tr>
<td>1103C</td>
<td>salbutamol 2 mg/5 mL oral liquid, 150 mL</td>
<td>2</td>
<td>5</td>
<td>..</td>
<td>22.54</td>
<td>..</td>
<td>23.69</td>
<td></td>
<td></td>
<td>Ventolin</td>
</tr>
<tr>
<td>1034K</td>
<td>terbutaline sulfate 500 microgram/mL injection, 5 x 1 mL ampoules</td>
<td>1</td>
<td>..</td>
<td>30.93</td>
<td>32.08</td>
<td>..</td>
<td></td>
<td></td>
<td></td>
<td>Bricanyl</td>
</tr>
</tbody>
</table>

**OTHER SYSTEMIC DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES**

### Xanthines

**THEOPHYLLINE**

**Caution**

Because of variable effects of food on absorption of sustained release theophylline preparations, patients stabilised on one brand should not be changed to another without appropriate monitoring.

**Note**

Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>Max. Qty $</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>Dispensed Price for Max. Qty $</th>
<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>2614N</td>
<td>theophylline 133.3 mg/25 mL oral liquid, 500 mL</td>
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<td>5</td>
<td>..</td>
<td>12.65</td>
<td>5</td>
<td>13.80</td>
<td></td>
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<td>Nuelin</td>
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<tr>
<td>8230E</td>
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<td>5</td>
<td>..</td>
<td>12.50</td>
<td>5</td>
<td>13.65</td>
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<td>Nuelin-SR 200</td>
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<tr>
<td>2634P</td>
<td>theophylline 250 mg tablet: modified release, 100 tablets</td>
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<td>Nuelin-SR 250</td>
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<td>8231F</td>
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<td>15.04</td>
<td>5</td>
<td>16.19</td>
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<td>Nuelin-SR 300</td>
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</table>

**Leukotriene receptor antagonists**

**MONTELUKAST**

**Authority required (STREAMLINED)**

2617

First-line preventer medication, as the single preventer agent for children aged 2 to 5 years with frequent intermittent or mild persistent asthma, as an alternative to sodium cromoglycate or nedocromil sodium

**Note**

Montelukast sodium is not PBS-subsidised for use in a child aged 2 to 5 years with moderate to severe asthma. It is not intended as an alternative for a child aged 2 to 5 years who requires a corticosteroid as a preventer medication.

Montelukast sodium is not subsidised in a child aged 2 to 5 years for use in combination with other preventer medications. PBS subsidy for montelukast sodium will therefore cease for a child aged 2 to 5 years who requires a preventer medication in addition to montelukast sodium.

**Note**

No applications for increased maximum quantities and/or repeats will be authorised.

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>Max. Qty $</th>
<th>No. of Rpts</th>
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<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>8627C</td>
<td>montelukast 4 mg tablet: chewable, 28</td>
<td>1</td>
<td>5</td>
<td>..</td>
<td>42.34</td>
<td>5</td>
<td>36.90</td>
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<td></td>
<td></td>
<td></td>
<td>APO-Montelukast TX</td>
<td>Auro-Montelukast Tabs 4</td>
<td>Chem mart</td>
<td>Montelukast</td>
<td>Lukair</td>
<td>Montelukast AN</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>TX</td>
<td>DO</td>
<td>CH</td>
<td>FR</td>
<td>GN</td>
<td>EA</td>
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</tbody>
</table>

**MONTELUKAST**

**Authority required (STREAMLINED)**

2618

First-line preventer medication, as the single preventer agent for children aged 6 to 14 years with frequent intermittent or mild persistent asthma, as an alternative to sodium cromoglycate or nedocromil sodium
**RESPIRATORY SYSTEM**

<table>
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<th>Name, Restriction, Manner of Administration and Form</th>
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<th>No. of Rpts</th>
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<th>Dispensed Price for Max. Qty $</th>
<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>3217</td>
<td>Prevention of exercise-induced asthma, as an alternative to adding salmeterol xinafoate or eformoterol fumarate, in a child aged 6 to 14 years whose asthma is otherwise well controlled while receiving optimal dose inhaled corticosteroid, but who requires short-acting beta-2 agonist 3 or more times per week for prevention or relief of residual exercise-related symptoms</td>
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<tr>
<td></td>
<td>Note Montelukast sodium is not PBS-subsidised for use in a patient aged 15 years or older, or for use in addition to a long-acting beta-agonist in any age group, or for use as a single second line preventer, as an alternative to corticosteroids, in a child aged 6 to 14 years with moderate to severe asthma.</td>
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<td></td>
<td>Note No applications for increased maximum quantities and/or repeats will be authorised.</td>
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<td>8628D</td>
<td>montelukast 5 mg tablet: chewable, 28 1 5 .. 40.36 36.90 a APO-Montelukast TX</td>
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<td>a Auro-Montelukast Tabs 5</td>
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<td>a Chem mart Montelukast</td>
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<td>a Lukair FR</td>
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<td>a Montair 5 GN</td>
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<td>a Montelukast GH GQ</td>
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<td>a Montelukast Sandoz 5 SZ</td>
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</table>

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**COUGH AND COLD PREPARATIONS**

**COUGH SUPPRESSANTS, EXCL. COMBINATIONS WITH EXPECTORANTS**

*Opium alkaloids and derivatives*

<table>
<thead>
<tr>
<th>CODE</th>
<th>Opium alkaloids and derivatives</th>
</tr>
</thead>
<tbody>
<tr>
<td>1214X</td>
<td>codeine phosphate 30 mg tablet, 20 1 .. .. 17.21 18.36 Fawns and McAllan Proprietary Limited FM</td>
</tr>
</tbody>
</table>

**ANTIHISTAMINES FOR SYSTEMIC USE**

**Phenothiazine derivatives**

<table>
<thead>
<tr>
<th>CODE</th>
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</thead>
<tbody>
<tr>
<td>194BM</td>
<td>promethazine hydrochloride 50 mg/2 mL injection, 5 x 2 mL ampoules 2 .. .. *30.58 31.73 Hospira Pty Limited HH</td>
</tr>
</tbody>
</table>
# SENSORY ORGANS

## OPHTHALMOLOGICALS

### ANTIINFECTIVES

#### Antibiotics

**AZITHROMYCIN**

**Restricted benefit**  
Trachoma

**Note**  
No applications for increased maximum quantities and/or repeats will be authorised.

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
<th>Dispensed Price for Max. Qty $</th>
<th>Premium $</th>
<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>8201P</td>
<td>azithromycin 200 mg/5 mL oral liquid: powder for, 15 mL</td>
<td>🇨🇦</td>
<td>..</td>
<td>#23.70</td>
<td>25.20</td>
<td>Zithromax</td>
<td>PF</td>
</tr>
<tr>
<td>8336R</td>
<td>azithromycin 500 mg tablet, 2</td>
<td>1</td>
<td>2</td>
<td>16.26</td>
<td>17.41</td>
<td>a</td>
<td>a</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Chloramphenicol 0.5% eye drops, 10 mL</td>
<td>18.63</td>
</tr>
<tr>
<td>2360F</td>
<td>chloramphenicol 0.5% eye drops, 10 mL</td>
<td>🇨🇦</td>
<td>2</td>
<td>..</td>
<td>11.34</td>
<td>12.49</td>
<td>Chloromycetin</td>
</tr>
<tr>
<td>5055C</td>
<td>chloramphenicol 0.5% eye drops, 10 mL</td>
<td>🇨🇦</td>
<td>..</td>
<td>..</td>
<td>11.34</td>
<td>12.49</td>
<td>Chloromycetin</td>
</tr>
<tr>
<td>5512D</td>
<td>chloramphenicol 0.5% eye drops, 10 mL</td>
<td>🇨🇦</td>
<td>2</td>
<td>..</td>
<td>11.34</td>
<td>12.49</td>
<td>Chloromycetin</td>
</tr>
<tr>
<td>1171P</td>
<td>chloramphenicol 1% eye ointment, 4 g</td>
<td>🇨🇦</td>
<td>..</td>
<td>..</td>
<td>10.10</td>
<td>11.25</td>
<td>Chloromycetin</td>
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<tr>
<td>5511C</td>
<td>chloramphenicol 1% eye ointment, 4 g</td>
<td>🇨🇦</td>
<td>..</td>
<td>..</td>
<td>10.10</td>
<td>11.25</td>
<td>Chloromycetin</td>
</tr>
</tbody>
</table>

**GENTAMICIN**

**Restricted benefit**

Invasive ocular infection  
Perioperative use in ophthalmic surgery  
Suspected pseudomonal eye infection

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
<th>Dispensed Price for Max. Qty $</th>
<th>Premium $</th>
<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1441W</td>
<td>gentamicin 0.3% eye drops, 5 mL</td>
<td>🇨🇦</td>
<td>2</td>
<td>..</td>
<td>18.63</td>
<td>19.78</td>
<td>Genoptic</td>
</tr>
</tbody>
</table>

**GENTAMICIN**

**Restricted benefit**

Perioperative use in ophthalmic surgery  
Suspected pseudomonal eye infection

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
<th>Dispensed Price for Max. Qty $</th>
<th>Premium $</th>
<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>5566Y</td>
<td>gentamicin 0.3% eye drops, 5 mL</td>
<td>🇨🇦</td>
<td>2</td>
<td>..</td>
<td>18.63</td>
<td>19.78</td>
<td>Genoptic</td>
</tr>
</tbody>
</table>

**TOBRAMYCIN**

**Restricted benefit**

Invasive ocular infection
### Sensory Organs

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
<th>Dispensed Price for Max. Qty $</th>
<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td></td>
<td><strong>Restricted benefit</strong> Perioperative use in ophthalmic surgery</td>
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<tr>
<td></td>
<td><strong>Restricted benefit</strong> Suspected pseudomonal eye infection</td>
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</tr>
<tr>
<td>2328M</td>
<td>tobramycin 0.3% (3 mg/mL) eye drops, 5 mL ‡1</td>
<td>₩1</td>
<td>2</td>
<td>19.62</td>
<td>20.77</td>
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</tr>
<tr>
<td>2329N</td>
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<td>₩1</td>
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<td>22.72</td>
<td>23.87</td>
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<td><strong>Restricted benefit</strong> Perioperative use in ophthalmic surgery</td>
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<td><strong>Restricted benefit</strong> Suspected pseudomonal eye infection</td>
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<td>20.77</td>
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<td>Tobrex AQ</td>
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<td></td>
<td><strong>Restricted benefit</strong> Herpes simplex keratitis</td>
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<td></td>
<td><strong>Note</strong></td>
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<tr>
<td></td>
<td>Shared Care Model: For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.</td>
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<td>37.80</td>
<td>36.90</td>
<td>Zovirax GK</td>
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<td><strong>Aciclovir</strong></td>
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<td><strong>Restricted benefit</strong> Herpes simplex keratitis</td>
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<td>37.80</td>
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<td>Zovirax GK</td>
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<td></td>
<td><strong>Authority required</strong> Bacterial keratitis</td>
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<td><strong>Treatment criteria:</strong> Must be treated by an ophthalmologist or in consultation with an ophthalmologist.</td>
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<tr>
<td>1217C</td>
<td>ciprofloxacin 0.3% eye drops, 5 mL ‡</td>
<td>₩2</td>
<td>..</td>
<td>*28.82</td>
<td>29.97</td>
<td>a CiloQuin IQ</td>
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<td>29.97</td>
<td>a CiloQuin IQ</td>
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### Sensory Organs

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**Corticosteroids and mydriatics in combination**

**Restricted benefit**

**Corneal grafts**

**Restricted benefit**

**Uveitis**

**PHENYLEPHRINE + PREDNISOLONE ACETATE**
### Sensory Organs

#### Sensory Organs

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### Parasympathomimetics

#### PILOCARPINE

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#### PILOCARPINE

**Note**

**Shared Care Model:**

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### Carbonic anhydrase inhibitors

#### ACETAZOLAMIDE

**Note**

**Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

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#### BRINZOLAMIDE

**Note**

**Shared Care Model:**

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#### BRINZOLAMIDE + TIMOLOL

**Restricted benefit**

**Elevated intra-ocular pressure**

**Clinical criteria:**

The condition must have been inadequately controlled with monotherapy,

**AND**

Patient must have open-angle glaucoma; OR

Patient must have ocular hypertension.

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## SENSORY ORGANS

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#### BETAXOLOL

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<tr>
<td>5546X</td>
<td>timolol 0.1% eye gel, 5 g</td>
<td>†1</td>
<td>5</td>
<td>...</td>
<td>13.21</td>
<td>14.36</td>
<td>Nyogel AS</td>
</tr>
<tr>
<td>5549C</td>
<td>timolol 0.25% (2.5 mg/mL) eye drops, 2.5 mL</td>
<td>†1</td>
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<td>5550D</td>
<td>timolol 0.5% (5 mg/mL) eye drops, 2.5 mL</td>
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<td>...</td>
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<td>Timoptol XE MK</td>
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<td>5548B</td>
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<td>5</td>
<td>...</td>
<td>12.65</td>
<td>13.80</td>
<td>Tenopt QA</td>
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</table>

#### Prostaglandin analogues

**BIMATOPROST**

**Note**

**Shared Care Model:**

For prescribing by optometrists where care of a patient is shared between an optometrist and ophthalmologist in a formalised arrangement with an agreed management plan. Further information can be found in the Guidelines for Shared Care of Glaucoma Patients.

<table>
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<tr>
<td>5551E</td>
<td>bimatoprost 0.03% eye drops, 3 mL</td>
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<td>5</td>
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<td>42.48</td>
<td>36.90</td>
<td>Lumigan AG</td>
</tr>
<tr>
<td>10053D</td>
<td>bimatoprost 0.03% eye drops, 30 x 0.4 mL unit doses</td>
<td>†1</td>
<td>5</td>
<td>...</td>
<td>36.91</td>
<td>36.90</td>
<td>Lumigan PF AG</td>
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</table>

**BIMATOPROST + TIMOLOL**

**Restricted benefit**

**Clinical criteria:**

The condition must have been inadequately controlled with monotherapy, **AND**
### SENSORY ORGANS

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
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<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>5558M OP</td>
<td>bimatoprost 0.03% + timolol 0.5% eye drops, 3 mL</td>
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<td>46.94</td>
<td>36.90</td>
<td>Ganfort 0.3/5</td>
<td>AG</td>
<td></td>
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<td>bimatoprost 0.03% + timolol 0.5% eye drops, 30 x 0.4 mL unit doses</td>
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<td>41.21</td>
<td>36.90</td>
<td>GANfort PF 0.3/5</td>
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<tr>
<td>9464D</td>
<td>bimatoprost 0.03% + timolol 0.5% eye drops, 3 mL</td>
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<td>41.21</td>
<td>36.90</td>
<td>GANfort PF 0.3/5</td>
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<td>latanoprost 0.005% eye drops, 2.5 mL</td>
<td>✡ 1 5 ..</td>
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<td>30.42</td>
<td>a APO-Latanoprost</td>
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<td>8243W</td>
<td>latanoprost 0.005% eye drops, 2.5 mL</td>
<td>✡ 1 5 ..</td>
<td>29.27</td>
<td>30.42</td>
<td>a APO-Latanoprost</td>
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**Note**

Shared Care Model:

For prescribing by optometrists where care of a patient is shared between an optometrist and ophthalmologist in a formalised arrangement with an agreed management plan. Further information can be found in the Guidelines for Shared Care of Glaucoma Patients.

**Shared Care Model:**

For prescribing by optometrists where care of a patient is shared between an optometrist and ophthalmologist in a formalised arrangement with an agreed management plan. Further information can be found in the Guidelines for Shared Care of Glaucoma Patients.
LATANOPROST + TIMOLOL

**Restricted benefit**

Elevated intra-ocular pressure

**Clinical criteria:**

The condition must have been inadequately controlled with monotherapy, AND

Patient must have open-angle glaucoma; OR

Patient must have ocular hypertension.

**Note**

**Shared Care Model:**

For prescribing by optometrists where care of a patient is shared between an optometrist and ophthalmologist in a formalised arrangement with an agreed management plan. Further information can be found in the Guidelines for Shared Care of Glaucoma Patients.

---

**LATANOPROST + TIMOLOL**

5553G OP latanoprost 0.005% + timolol 0.5% eye drops, 2.5 mL ‡1 5 41.21 36.90 Latanocom, FZ Latanoprost/Timolol Sandoz, SZ Xalacom, PF

---

**LATANOPROST + TIMOLOL**

8895E latanoprost 0.005% + timolol 0.5% eye drops, 2.5 mL ‡1 5 41.21 36.90 APO-Latanoprost/Timolol 0.05/5 Latanocom, FZ Latanoprost/Timolol Sandoz 50/5 Xalacom, PF

---

**TAFLUPROST**

**Note**

**Shared Care Model:**

For prescribing by optometrists where care of a patient is shared between an optometrist and ophthalmologist in a formalised arrangement with an agreed management plan. Further information can be found in the Guidelines for Shared Care of Glaucoma Patients.

---

**TAFLUPROST**

2748P OP tafluprost 0.0015% eye drops, 30 x 0.3 mL unit doses ‡1 5 34.16 35.31 Saflutan, MK

---

**TIMOLOL + TRAVOPROST**

**Restricted benefit**

Elevated intra-ocular pressure

**Clinical criteria:**

The condition must have been inadequately controlled with monotherapy, AND

Patient must have open-angle glaucoma; OR

Patient must have ocular hypertension.

**Note**

**Shared Care Model:**

For prescribing by optometrists where care of a patient is shared between an optometrist and ophthalmologist in a formalised arrangement with an...
**SENSORY ORGANS**

<table>
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<tr>
<td>5555J</td>
<td>timolol 0.5% + travoprost 0.004% eye drops, 2.5 mL</td>
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<td>5</td>
<td>..</td>
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<td>36.90</td>
<td>Duotrav AQ</td>
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</table>

**TIMOLOL + TRAVOPROST**

**Restricted benefit**

Elevated intra-ocular pressure

**Clinical criteria:**

The condition must have been inadequately controlled with monotherapy, AND

Patient must have open-angle glaucoma; OR

Patient must have ocular hypertension.

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<td>9057Q</td>
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<td>Duotrav AQ</td>
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**TRAVOPROST**

**Note**

Shared Care Model:

For prescribing by optometrists where care of a patient is shared between an optometrist and ophthalmologist in a formalised arrangement with an agreed management plan. Further information can be found in the Guidelines for Shared Care of Glaucoma Patients.

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<tr>
<td>5554H</td>
<td>travoprost 0.004% (40 microgram/mL) eye drops, 2.5 mL</td>
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<td>5</td>
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<td>Travatan AQ</td>
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**MYDRIATICS AND CYCLOPLEGICS**

**Anticholinergics**

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<tr>
<td>1093M</td>
<td>ATROPINE Eye drops containing atropine sulfate 10 mg per mL (1%), 15 mL, 1</td>
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<td>2</td>
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<td>22.11</td>
<td>23.26</td>
<td>Atropt QA</td>
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<tr>
<td>10063P</td>
<td>homatropine hydrobromide 2% eye drops, 15 mL</td>
<td>‡1</td>
<td>2</td>
<td>..</td>
<td>19.15</td>
<td>20.30</td>
<td>Isopto Homatropine AQ</td>
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<tr>
<td>2541R</td>
<td>homatropine hydrobromide 2% eye drops, 15 mL</td>
<td>‡1</td>
<td>2</td>
<td>..</td>
<td>19.15</td>
<td>20.30</td>
<td>Isopto Homatropine AQ</td>
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**DECONGESTANTS AND ANTIALLERGICS**

**Other antiallergics**

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<tr>
<td>1127H</td>
<td>cromoglicate sodium 2% eye drops, 10 mL</td>
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<td>14.55</td>
<td>15.70</td>
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<tr>
<td>5529B</td>
<td>cromoglicate sodium 2% eye drops, 10 mL</td>
<td>‡1</td>
<td>5</td>
<td>..</td>
<td>14.55</td>
<td>15.70</td>
<td>Opticrom a AE a</td>
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**OCULAR VASCULAR DISORDER AGENTS**

**Antineovascularisation agents**

**AFLIBERCEPT**

**Authority required**

Subfoveal choroidal neovascularisation (CNV)

Treatment Phase: Initial treatment

**Clinical criteria:**

The condition must be due to age-related macular degeneration (AMD), AND
The condition must be diagnosed by fluorescein angiography, AND

The treatment must be the sole PBS-subsidised therapy for this condition.

Treatment criteria:
Must be treated by an ophthalmologist.
Authority approval for initial treatment of each eye must be sought.
The first authority application for each eye must be made in writing or by telephone.
A written application must include:
   a) a completed authority prescription form;
   b) a completed Subfoveal Choroidal Neovascularisation (CNV) - PBS Supporting Information Form; and
   c) a copy of the fluorescein angiogram.
A telephone application must be made following submission by facsimile of a copy of a completed Subfoveal Choroidal Neovascularisation (CNV) - PBS Supporting Information Form and a copy of the fluorescein angiogram. The original documentation must be submitted to the Chief Executive Medicare by post after the application has been authorised.
Where a fluorescein angiogram cannot be performed due to a contraindication as listed in the TGA-approved product information, details of the contraindication must be provided. A copy of the report of an alternative method of diagnosis must be included in the application, for example, optical coherence tomography (OCT) or red free photography.

Note
The first authority application may be faxed to the Department of Human Services on 1300 093 177 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). The Department will then contact the prescriber by telephone.

Note
Authority approvals will be administered by the Complex Drugs Unit of the Department of Human Services.

Note
Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Note
Special Pricing Arrangements apply.

Authority required
Subfoveal choroidal neovascularisation (CNV)
Treatment Phase: Continuing treatment

Clinical criteria:
The condition must be due to age-related macular degeneration (AMD), AND

The treatment must be the sole PBS-subsidised therapy for this condition, AND

Patient must have previously been granted an authority prescription for the same eye.

Treatment criteria:
Must be treated by an ophthalmologist.

Note
Authority approvals will be administered by the Complex Drugs Unit of the Department of Human Services.

Note
Authority applications for continuing treatment in the same eye may be made by telephone on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Note
No increase in the maximum number of repeats may be authorised.

Note
### SENSORY ORGANS

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<tr>
<td>2168D</td>
<td>aflibercept 4 mg/0.1 mL injection, 1 x 0.1 mL vial</td>
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<td>2</td>
<td>..</td>
<td>1431.50</td>
<td>36.90</td>
<td>Eylea BN</td>
</tr>
</tbody>
</table>

**RANIBIZUMAB**

*Authority required*

Subfoveal choroidal neovascularisation (CNV)

**Treatment Phase: Initial treatment**

**Clinical criteria:**

The condition must be due to age-related macular degeneration (AMD),

AND

The condition must be diagnosed by fluorescein angiography,

AND

The treatment must be the sole PBS-subsidised therapy for this condition.

**Treatment criteria:**

Must be treated by an ophthalmologist.

Authority approval for initial treatment of each eye must be sought.

The first authority application for each eye must be made in writing or by telephone.

A written application must include:

a) a completed authority prescription form;

b) a completed Subfoveal Choroidal Neovascularisation (CNV) - PBS Supporting Information Form; and

c) a copy of the fluorescein angiogram.

A telephone application must be made following submission by facsimile of a copy of a completed Subfoveal Choroidal Neovascularisation (CNV) - PBS Supporting Information Form and a copy of the fluorescein angiogram. The original documentation must be submitted to the Chief Executive Medicare by post after the application has been authorised.

Where a fluorescein angiogram cannot be performed due to a contraindication as listed in the TGA-approved product information, details of the contraindication must be provided. A copy of the report of an alternative method of diagnosis must be included in the application, for example, optical coherence tomography (OCT) or red free photography.

**Note**

The first authority application may be faxed to the Department of Human Services on 1300 093 177 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). The Department will then contact the prescriber by telephone.

**Note**

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

**Note**

Special Pricing Arrangements apply.

*Authority required*

Subfoveal choroidal neovascularisation (CNV)

**Treatment Phase: Continuing treatment**

**Clinical criteria:**

The condition must be due to age-related macular degeneration (AMD),

AND

The treatment must be the sole PBS-subsidised therapy for this condition,

AND

Patient must have previously been granted an authority prescription for the same eye.

**Treatment criteria:**
SENSORY ORGANS

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<td>10138N</td>
<td>ranibizumab 1.65 mg/0.165 mL injection, 1 x 0.165 mL syringe</td>
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<td>2</td>
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<td>36.90</td>
<td>Lucentis NV</td>
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<tr>
<td>1382R</td>
<td>ranibizumab 2.3 mg/0.23 mL injection, 1 x 0.23 mL vial</td>
<td>1</td>
<td>2</td>
<td>1431.50</td>
<td>36.90</td>
<td>Lucentis NV</td>
</tr>
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</table>

**VERTEPORFIN**

**Authority required**

Initial treatment by an ophthalmologist, as the sole PBS-subsidised therapy, of predominantly (greater than or equal to 50%) classic, subfoveal choroidal neovascularisation (CNV) due to age-related macular degeneration (AMD), as diagnosed by fluorescein angiography, in a patient with a baseline visual acuity equal to or better than 6/60 (20/200).

Authority approvals will be administered by the PBS and Specialised Drugs Branch of Medicare Australia.

The first authority application for each eye must be made in writing, and must include:

(a) a completed authority prescription form; and

(b) a completed Subfoveal Choroidal Neovascularisation (CNV) - PBS Supporting Information Form [www.medicareaustralia.gov.au]; and

(c) a copy of the fluorescein angiogram demonstrating that the CNV is predominantly classic (greater than or equal to 50%).

Written applications for authority to prescribe verteporfin should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

Alternatively, the first authority application may be faxed to Medicare Australia on 1300 093 177 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Medicare Australia will then contact the prescriber by telephone. The original documentation must be posted to the above address after approval has been gained.

No more than 15 treatments (1 initial and 14 continuing) per eye will be authorised.

Medicare Australia should be notified if treatment is abandoned prior to completion of the laser activation step but after infusion of verteporfin. Telephone 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). The reason treatment is abandoned must be provided. Where such notification has been made, the treatment so affected will not count towards the maximum

**Authority required**

Initial PBS-subsidised treatment by an ophthalmologist, as the sole PBS-subsidised therapy, of predominantly (greater than or equal to 50%) classic, subfoveal choroidal neovascularisation (CNV) due to macular degeneration where the patient has been authorised by the Angiogram Review Panel to receive treatment with verteporfin in the same eye under the MBS Visudyne Therapy Program.

Authority approvals will be administered by the PBS and Specialised Drugs Branch of Medicare Australia.

The first authority application for each eye must be made in writing, and must include:

(a) a completed authority prescription form; and

(b) a completed Subfoveal Choroidal Neovascularisation (CNV) - PBS Supporting Information Form [www.medicareaustralia.gov.au], which includes the date of review by the Angiogram Review Panel and the number of treatments administered in that eye under the MBS Visudyne Therapy Program; and

(c) a copy of the fluorescein angiogram demonstrating that the CNV is predominantly classic (greater than or equal to 50%).

Written applications for authority to prescribe verteporfin should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

Alternatively, the first authority application may be faxed to Medicare Australia on 1300 093 177 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Medicare Australia will then contact the prescriber by telephone. The original documentation must be posted to the above address after approval has been gained.

A patient is eligible for a total of 15 subsidised treatments per eye. This maximum includes treatments administered under the MBS Visudyne Therapy Program and the PBS.
Medicare Australia should be notified if treatment is abandoned prior to completion of the laser activation step but after infusion of verteporfin. Telephone 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). The reason treatment is abandoned must be provided. Where such notification has been made, the treatment so affected will not count towards the maximum.

**Authority required**
Continuing treatment by an ophthalmologist, as the sole PBS-subsidised therapy, of predominantly (greater than or equal to 50%) classic, subfoveal choroidal neovascularisation (CNV) due to macular degeneration where the patient has previously been granted an authority prescription for the same eye.

A patient is eligible for a total of 15 subsidised treatments per eye. This maximum includes treatments administered under the MBS Visudyne Therapy Program and the PBS.

Medicare Australia should be notified if treatment is abandoned prior to completion of the laser activation step but after infusion of verteporfin. Telephone 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). The reason treatment is abandoned must be provided. Where such notification has been made, the treatment so affected will not count towards the maximum.

Authority approvals will be administered by the PBS and Specialised Drugs Branch of Medicare Australia. Authority applications for continuing treatment in the same eye may be made by telephone on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

### SENSORY ORGANS

#### Code

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### OTHER OPHTHALMOLOGICALS

**Other ophthalmologicals**

**CARBOMER + TRIGLYCERIDE LIPIDS**

**Authority required (STREAMLINED)**

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<td>carbomer 0.2% + triglyceride lipids 1% eye gel, 30 x 600 mg unit doses</td>
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<td>11.15</td>
<td>Optifresh eye gel a PP PAA IQ</td>
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a. Optifresh eye gel PP
b. PAA IQ
### SENSORY ORGANS

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### CARBOMER-980

**Restrictive benefit**

For use in patients who have severe dry eye syndrome, including Sjogren's syndrome, and who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements

**Note**

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<td>11.84</td>
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### CARMELLOSE SODIUM

**Restrictive benefit**

Severe dry eye syndrome, including Sjogren's syndrome

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### CARMELLOSE SODIUM

**Restrictive benefit**

Severe dry eye syndrome in patients who are sensitive to preservatives in multi-dose eye drops

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<td>8823J</td>
<td>carmellose sodium 0.25% (1.5 mg/0.6 mL) eye drops, 24 x 0.6 mL unit doses</td>
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<td>5</td>
<td>*40.76</td>
<td>36.90</td>
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<td>2338C</td>
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<td>*31.63</td>
<td>32.78</td>
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<td>8824K</td>
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### CARMELLOSE SODIUM

**Authority required**

Severe dry eye syndrome in patients who are sensitive to preservatives in multi-dose eye drops

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<td>4.77</td>
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<td>5556K</td>
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<td>12.08</td>
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<td>..</td>
<td>*35.41</td>
<td>36.56</td>
<td>Bion Tears AQ</td>
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### SENSORY ORGANS

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**DEXTRAN-70 + HYPMELLOSE**  
**Authority required (STREAMLINED)**  
Authority required (STREAMLINED)

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| 1359  | Severe dry eye syndrome in patients who are sensitive to preservatives in multi-dose eye drops  
Dextran-70 0.1% + hypermellose 0.3% eye drops, 28 x 0.4 mL unit doses | 3                | 5           | *35.41                                      | 36.56                                    | Bion Tears AQ             |

**HYPMELLOSE**  
**Restricted benefit**
Severe dry eye syndrome, including Sjogren's syndrome

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<th>10.61</th>
<th>11.76</th>
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<table>
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<th>HYPMELLOSE Eye drops 3 mg per mL (0.3%), 15 mL (contains sodium perborate as preservative), 1</th>
<th>†1</th>
<th>5</th>
<th>10.61</th>
<th>11.76</th>
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**HYPMELLOSE**  
**Restricted benefit**
For use in patients who have severe dry eye syndrome, including Sjogren's syndrome, and who are receiving treatment under a General Practitioner (GP) Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements

**Note**
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| HYPROMELLOSE + CARBOMER-980  
Restricted benefit  
Severe dry eye syndrome, including Sjogren's syndrome | †1               | 11           | 10.61                                      | 11.76                                    | In a Wink Moisturising IQ   |
|-------|-------------------------------------------------------------------------------------------------------------------------|------------------|-------------|--------------------------------|------------------------------------------|---------------------------|

| HYPROMELLOSE + CARBOMER-980  
Restricted benefit  
For use in patients who have severe dry eye syndrome, including Sjogren's syndrome, and who are receiving treatment under a General Practitioner (GP) Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements | †1               | 11           | 10.61                                      | 11.76                                    | In a Wink Moisturising IQ   |
|-------|-------------------------------------------------------------------------------------------------------------------------|------------------|-------------|------------------------------------------|------------------------------------------|---------------------------|

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<th>5</th>
<th>20.94</th>
<th>22.09</th>
<th>Ircal PE AG</th>
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<th>20.94</th>
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<th>Ircal PE AG</th>
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## SENSORY ORGANS

### PARAFFIN

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**PARAFFIN**

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</table>

**PARAFFIN**

**Note**
The in-use shelf life of VitA-POS is 6 months from the date of opening.

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
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<th>Premium $</th>
<th>Dispensed Price for Max. Qty $</th>
<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>2167C</td>
<td>paraffin + retinyl palmitate 138 microgram/g (equivalent to 250 units/g vitamin A) eye ointment, 5 g</td>
<td>2</td>
<td>5</td>
<td>..</td>
<td>2.12</td>
<td>23.06</td>
<td>a  Poly Visc Refresh Night Time AG</td>
</tr>
<tr>
<td></td>
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<td></td>
<td></td>
<td></td>
<td>Blink Intensive Tears AO</td>
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<tr>
<td>2222Y</td>
<td>paraffin + retinyl palmitate 138 microgram/g (equivalent to 250 units/g vitamin A) eye ointment, 5 g</td>
<td>2</td>
<td>5</td>
<td>..</td>
<td>2.54</td>
<td>24.12</td>
<td>a  Duratears AQ</td>
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<td>Blink Intensive Tears AO</td>
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**PARAFFIN**

**Note**
The in-use shelf life of VitA-POS is 6 months from the date of opening.

**Note**
No increase in the maximum quantity or number of units may be authorised.

**Note**
No increase in the maximum number of repeats may be authorised.

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<td>11</td>
<td>..</td>
<td>2.12</td>
<td>23.06</td>
<td>a  Poly Visc Refresh Night Time AG</td>
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<tr>
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<td>Blink Intensive Tears AO</td>
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**POLYETHYLENE GLYCOL-400**

**Restricted benefit**
Severe dry eye syndrome, including Sjogren's syndrome

**Note**
The in-use shelf life of Blink Intensive Tears multi-dose formulation is 45 days from the date of opening.

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<tbody>
<tr>
<td>5559N</td>
<td>polyethylene glycol-400 0.25% eye drops, 15 mL</td>
<td>‡1</td>
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<td>9491M</td>
<td>polyethylene glycol-400 0.25% eye drops, 15 mL</td>
<td>‡1</td>
<td>5</td>
<td>..</td>
<td>2.12</td>
<td>23.06</td>
<td>a  Blink Intensive Tears AO</td>
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</tbody>
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**POLYETHYLENE GLYCOL-400**

**Restricted benefit**
For use in patients who have severe dry eye syndrome, including Sjogren's syndrome, and who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.

**Note**
No applications for increased maximum quantities and/or repeats will be authorised.
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<thead>
<tr>
<th>Code</th>
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<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>9492N</td>
<td>polyethylene glycol-400 0.25% eye drops, 15 mL</td>
<td>10.93</td>
<td>12.08</td>
<td>Blink Intensive Tears AO</td>
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<td><strong>POLYETHYLENE GLYCOL-400</strong></td>
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<td></td>
<td><strong>Authority required</strong></td>
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<tr>
<td></td>
<td>Severe dry eye syndrome in patients who are sensitive to preservatives in multi-dose eye drops</td>
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<tr>
<td>5560P</td>
<td>polyethylene glycol-400 0.25% eye drops, 20 x 0.4 mL unit doses</td>
<td>*39.71</td>
<td>36.90</td>
<td>Blink Intensive Tears AO</td>
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<td></td>
<td>Severe dry eye syndrome in patients who are sensitive to preservatives in multi-dose eye drops</td>
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<td></td>
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</tr>
<tr>
<td>9493P</td>
<td>polyethylene glycol-400 0.25% eye drops, 20 x 0.4 mL unit doses</td>
<td>*39.71</td>
<td>36.90</td>
<td>Blink Intensive Tears AO</td>
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<tr>
<td>NP</td>
<td><strong>POLYETHYLENE GLYCOL-400 + PROPYLENE GLYCOL</strong></td>
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<td><strong>Restricted benefit</strong></td>
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<tr>
<td></td>
<td>Severe dry eye syndrome, including Sjogren's syndrome</td>
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<tr>
<td>5524R</td>
<td>polyethylene glycol-400 0.4% + propylene glycol 0.3% eye drops, 15 mL</td>
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<td>Systane AQ</td>
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<td>For use in patients who have severe dry eye syndrome, including Sjogren's syndrome, and who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements</td>
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<td>12.08</td>
<td>Systane AQ</td>
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<tr>
<td></td>
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<td>Severe dry eye syndrome in patients who are sensitive to preservatives in multi-dose eye drops</td>
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<tr>
<td>5532E</td>
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<td>35.57</td>
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<tr>
<td>9170P</td>
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<tr>
<td>2682E</td>
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<td>11.76</td>
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<td><strong>POLYVINYLM ALCOHOL</strong></td>
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<tr>
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<td></td>
<td><strong>Restricted benefit</strong></td>
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<tr>
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<td>a Liquifilm Tears AG</td>
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<td><strong>Restricted benefit</strong></td>
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<td>Severe dry eye syndrome, including Sjogren's syndrome</td>
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<tr>
<td>8831T</td>
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<td>12.21</td>
<td>11.76</td>
<td>a Vistil AE</td>
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<tr>
<td>NP</td>
<td><strong>POLYVINYLM ALCOHOL</strong></td>
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### SENSORY ORGANS

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<td>‡1 5</td>
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<td>11.76</td>
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<td>a</td>
<td>Liquifilm Forte AG</td>
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<tr>
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<td>...</td>
<td>10.61</td>
<td>11.76</td>
<td>Vistil Forte AE</td>
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</tbody>
</table>

**POLYVINYL ALCOHOL**

**Restricted benefit**

For use in patients who have severe dry eye syndrome, including Sjogren’s syndrome, and who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements

**Note**

No applications for increased maximum quantities and/or repeats will be authorised.

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<td>9221H</td>
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<td>‡1 11</td>
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<td>11.76</td>
<td>a</td>
<td>Liquifilm Tears AG</td>
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<tr>
<td>9222J</td>
<td>polyvinyl alcohol 3% eye drops, 15 mL</td>
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<td>...</td>
<td>10.61</td>
<td>11.76</td>
<td>a</td>
<td>Vistil AE</td>
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<td>‡1 11</td>
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<td>10.61</td>
<td>11.76</td>
<td>Vistil Forte AE</td>
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**SODIUM HYALURONATE**

**Authority required (STREAMLINED)**

4105

Severe dry eye syndrome

**Clinical criteria:**

Patient must be sensitive to preservatives in multi-dose eye drops.

**Note**

The in-use shelf life of Hylo-Fresh and Hylo-Forte is 6 months from the date of opening.

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<tr>
<th>Code</th>
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<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>2181T</td>
<td>sodium hyaluronate 0.1% (1 mg/mL) eye drops, 10 mL</td>
<td>‡1 5</td>
<td>...</td>
<td>33.96</td>
<td>35.11</td>
<td>Hylo-Fresh AE</td>
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<td>2253N</td>
<td>sodium hyaluronate 0.2% (2 mg/mL) eye drops, 10 mL</td>
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<td>33.96</td>
<td>35.11</td>
<td>Hylo-Forte AE</td>
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**SODIUM HYALURONATE**

**Authority required**

Severe dry eye syndrome

**Clinical criteria:**

Patient must be sensitive to preservatives in multi-dose eye drops.

**Note**

The in-use shelf life of Hylo-Fresh and Hylo-Forte is 6 months from the date of opening.

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<td>‡1 5</td>
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<tr>
<td>2171G</td>
<td>sodium hyaluronate 0.2% (2 mg/mL) eye drops, 10 mL</td>
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<td>33.96</td>
<td>35.11</td>
<td>Hylo-Forte AE</td>
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**SOY LECITHIN + TOCOPHEROLS + VITAMIN A**

**Authority required**

Severe dry eye syndrome in patients who are sensitive to preservatives in multi-dose eye drops

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<tr>
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<tr>
<td>5545W</td>
<td>soy lecithin 1% (10 mg/mL) + tocopherols 0.002% (20 microgram/mL) + vitamin A palmitate 0.025% (250 microgram/mL) eye spray, 100 actuations</td>
<td>2 5</td>
<td>...</td>
<td>*36.40</td>
<td>36.90</td>
<td>tearsagain RB</td>
<td></td>
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</table>
### SENSORY ORGANS

<table>
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<th>Name, Restriction, Manner of Administration and Form</th>
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<tr>
<td>1359</td>
<td>Severe dry eye syndrome in patients who are sensitive to preservatives in multi-dose eye drops</td>
<td>9448G</td>
<td>soy lecithin 1% (10 mg/mL) + tocopherols 0.002% (20 microgram/mL) + vitamin A palmitate 0.025% (250 microgram/mL) eye spray, 100 actuations</td>
<td>2</td>
<td>5</td>
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### OTOLOGICALS

#### ANTIINFECTIVES

**Antiinfectives**

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<tr>
<td>1172Q</td>
<td>chloramphenicol 0.5% ear drops, 5 mL</td>
<td>‡1</td>
<td>2</td>
<td>11.39</td>
<td>12.54</td>
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<td>Chloromycetin</td>
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<td></td>
<td>framycetin sulfate 0.5% (5 mg/mL) eye/ear drops, 8 mL</td>
<td>‡1</td>
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<td>11.43</td>
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<td>Soframycin</td>
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<td>2480M</td>
<td>ciprofloxacin 0.3% ear drops, 5 mL</td>
<td>‡1</td>
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<td>19.62</td>
<td>20.77</td>
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<td>Ciloxan</td>
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### CORTICOSTEROIDS AND ANTIINFECTIVES IN COMBINATION

**Corticosteroids and antiinfectives in combination**

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<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
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<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>2781J</td>
<td>dexamethasone 0.05% (500 microgram/mL) + framycetin sulfate 0.5% (5 mg/mL) + gramicidin 0.005% (50 microgram/mL) ear drops, 8 mL</td>
<td>‡1</td>
<td>2</td>
<td>8.52</td>
<td>9.67</td>
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<td>Otoject</td>
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<tr>
<td></td>
<td>triamcinolone acetate 0.1% + neomycin sulfate 0.25% + gramicidin 0.025% + nystatin 100 000 international units/mL ear drops, 7.5 mL</td>
<td>‡1</td>
<td>2</td>
<td>8.52</td>
<td>9.67</td>
<td></td>
<td>Kenacomb Otic</td>
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### OPHTHALMOLOGICAL AND OTOLOGICAL PREPARATIONS

#### ANTIINFECTIVES

**Antiinfectives**

<table>
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<tr>
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<th>Name, Restriction, Manner of Administration and Form</th>
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<th>Premium $</th>
<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>1440T</td>
<td>framycetin sulfate 0.5% (5 mg/mL) eye/ear drops, 8 mL</td>
<td>‡1</td>
<td>2</td>
<td>11.08</td>
<td>12.23</td>
<td></td>
<td>Soframycin</td>
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<tr>
<td>5557L</td>
<td>framycetin sulfate 0.5% (5 mg/mL) eye/ear drops, 8 mL</td>
<td>‡1</td>
<td>2</td>
<td>11.08</td>
<td>12.23</td>
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<td>Soframycin</td>
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### ALLERGENS

**Allergen extracts**

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<tbody>
<tr>
<td>2886X</td>
<td>Bee venom 550 microgram injection [1 x 550 microgram vial] (&amp;) inert substance diluent [4 vials], 1 pack</td>
<td>1</td>
<td>..</td>
<td>..</td>
<td>238.72</td>
<td>36.90</td>
<td>Albey Bee Venom HL</td>
</tr>
<tr>
<td>2918N</td>
<td>Paper wasp venom 550 microgram injection [1 x 550 microgram vial] (&amp;) inert substance diluent [4 vials], 1 pack</td>
<td>1</td>
<td>..</td>
<td>..</td>
<td>238.72</td>
<td>36.90</td>
<td>Albey Paper Wasp Venom HL</td>
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<tr>
<td>2883R</td>
<td>Vespula spp venom 550 microgram injection [1 x 550 microgram vial] (&amp;) inert substance diluent [4 vials], 1 pack</td>
<td>1</td>
<td>..</td>
<td>..</td>
<td>238.72</td>
<td>36.90</td>
<td>Albey Yellow Jacket Venom HL</td>
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**Note**

Paper wasp venom is not European wasp venom.

### ALL OTHER THERAPEUTIC PRODUCTS

**Antidotes**

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<tr>
<td>2192J</td>
<td>Naloxone hydrochloride 400 microgram/mL injection, 1 x 1 mL syringe</td>
<td>5</td>
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<td>..</td>
<td>*105.16</td>
<td>36.90</td>
<td>Naloxone minijet UC</td>
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<td>2196N</td>
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<td>..</td>
<td>..</td>
<td>*105.16</td>
<td>36.90</td>
<td>Naloxone minijet UC</td>
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**Drugs for treatment of hyperkalemia and hyperphosphatemia**

**LANTHANUM**

**Authority required (STREAMLINED) 3546**

Maintenance therapy, following initiation and stabilisation of treatment with lanthanum carbonate, of hyperphosphataemia in a patient with chronic kidney disease on dialysis whose serum phosphate is not controlled on calcium and where serum phosphate is greater than 1.6 mmol per L at the commencement of therapy.

**Authority required (STREAMLINED) 3547**

Maintenance therapy, following initiation and stabilisation of treatment with lanthanum carbonate, of hyperphosphataemia in a patient with chronic kidney disease on dialysis whose serum phosphate is not controlled on calcium and where the serum calcium times phosphate product is greater than 4.0 at the commencement of therapy.

**Note**

Not to be used in combination with sevelamer.

**Note**

Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and a medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

<table>
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<tr>
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<tr>
<td>9405B</td>
<td>LANTHANUM Tablet, chewable, 1000 mg (as carbonate hydrate), 90</td>
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<td>Fosrenol ZI</td>
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<tr>
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<td>LANTHANUM Tablet, chewable, 500 mg (as carbonate hydrate), 90</td>
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<td>Fosrenol ZI</td>
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<tr>
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**SEVELAMER**
### Various

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</table>

#### Authority required (STREAMLINED)

**3548**
Maintenance therapy, following initiation and stabilisation of treatment with sevelamer hydrochloride, of hyperphosphataemia in a patient with chronic kidney disease on dialysis whose serum phosphate is not controlled on calcium and where serum phosphate is greater than 1.6 mmol per L at the commencement of therapy

**3549**
Maintenance therapy, following initiation and stabilisation of treatment with sevelamer hydrochloride, of hyperphosphataemia in a patient with chronic kidney disease on dialysis whose serum phosphate is not controlled on calcium and where the serum calcium times phosphate product is greater than 4.0 at the commencement of therapy

**Note**
Not to be used in combination with lanthanum.

#### Detoxifying agents for antineoplastic treatment

**FOLINIC ACID**

**8969C**
folinic acid 1 g/100 mL injection, 1 x 100 mL vial  1  1  ...  71.63  36.90  Calcium Folinate Ebewe  SZ

**9041W**
folinic acid 300 mg/30 mL injection, 1 x 30 mL vial  4  1  ...  *82.72  36.90  a  Calcium Folinate Ebewe  SZ  a  Leucovorin Calcium (Hospira Pty Limited)

**8812T**
folinic acid 100 mg/10 mL injection, 1 x 10 mL vial  10  1  ...  *71.66  36.90  a  Calcium Folinate Ebewe  SZ

**1704Q**
folinic acid 100 mg/10 mL injection, 10 x 10 mL ampoules  1  1  ...  71.69  36.90  a  Leucovorin Calcium (Pfizer Australia Pty Ltd)

**2308L**
folinic acid 15 mg tablet, 10  1  ...  96.65  36.90  Leucovorin Calcium (Hospira Pty Limited)

**FOLINIC ACID**

**Note**
For item codes 8812T and 1704Q, pharmaceutical benefits that have the form injection equivalent to 100 mg folinic acid in 10 mL are equivalent for the purposes of substitution.

**8740B**
folinic acid 50 mg/5 mL injection, 1 x 5 mL vial  10  2  ...  *77.06  36.90  a  Leucovorin Calcium (Hospira Pty Limited)  HH

**1610R**
folinic acid 50 mg/5 mL injection, 10 x 5 mL ampoules  1  2  ...  77.02  36.90  a  Leucovorin Calcium (Pfizer Australia Pty Ltd)  PF

**1575X**
folinic acid 50 mg/5 mL injection, 5 x 5 mL ampoules  2  2  ...  *77.00  36.90  a  Calcium Folinate Ebewe  SZ

**MESNA**

**Restricted benefit**
Adjunctive therapy for use with ifosfamide or high dose cyclophosphamide

**8079F**
mesna 1 g/10 mL injection, 15 x 10 mL ampoules  1  5  ...  224.15  36.90  Uromitexan  BX

**8078E**
mesna 400 mg/4 mL injection, 15 x 4 mL ampoules  1  5  ...  103.62  36.90  Uromitexan  BX

**Drugs for treatment of hypercalcemia**
PHOSPHORUS

Authority required (STREAMLINED)

1099
Familial hypophosphataemia

Authority required (STREAMLINED)

1157
Hypercalcaemia

Authority required (STREAMLINED)

1167
Hypophosphataemic rickets

Authority required (STREAMLINED)

1467
Vitamin D-resistant rickets

Other therapeutic products

POLYLACTIC ACID

Authority required

Initial PBS-subsidised treatment, for facial administration only, of severe facial lipoatrophy caused by therapy for HIV infection.

Accreditation following completion of injection administration training with Sanofi-Aventis is required to prescribe poly-l-lactic acid under the PBS. Patients must be referred from the HIV physician to the accredited injector

Note
Authority applications to prescribe poly-l-lactic acid may be made by telephone to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Note
No applications for increased maximum quantities and/or repeats will be authorised.

POLYLACTIC ACID

Authority required

Maintenance PBS-subsidised treatment, for facial administration only, of severe facial lipoatrophy caused by therapy for HIV infection.

Accreditation following completion of injection administration training with Sanofi-Aventis is required to prescribe poly-l-lactic acid under the PBS. Patients must be referred from the HIV physician to the accredited injector

Note
Authority applications to prescribe poly-l-lactic acid may be made by telephone to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Note
No applications for increased maximum quantities and/or repeats will be authorised.

Maintenance treatment is limited to one re-treatment (maximum 2 vials) every 2 years.

GLUCOSE AND KETONE INDICATOR URINE

Restricted benefit
For use in patients who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements

Note
No applications for increased maximum quantities and/or repeats will be authorised.
## VARIOUS

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<td>strip: diagnostic, 50 diagnostic strips glucose and ketone indicator urine strip: diagnostic, 50 diagnostic strips</td>
<td>2</td>
<td>4</td>
<td>..</td>
<td>*17.76</td>
<td>18.91</td>
<td>Keto-Diastix BN</td>
</tr>
<tr>
<td>3104J</td>
<td>glucose indicator urine strip: diagnostic, 50 diagnostic strips</td>
<td>2</td>
<td>2</td>
<td>..</td>
<td>*20.16</td>
<td>21.31</td>
<td>Diastix BN</td>
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### GLUCOSE INDICATOR URINE

**Restricted benefit**

For use in patients who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.

**Note**

No applications for increased maximum quantities and/or repeats will be authorised.

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<td>4</td>
<td>..</td>
<td>*20.16</td>
<td>21.31</td>
<td>Diastix BN</td>
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</table>

### OTHER DIAGNOSTIC AGENTS

#### Tests for diabetes

**GLUCOSE INDICATOR BLOOD**

**Restricted benefit**

Blood glucose monitoring

**Clinical criteria:**

Patient must be receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.

**Note**

No increase in the maximum quantity or number of units may be authorised.

**Note**

No increase in the maximum number of repeats may be authorised.

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<td>36.90</td>
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<td>11</td>
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<td>11</td>
<td></td>
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**GLUCOSE INDICATOR BLOOD**

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**GLUCOSE INDICATOR BLOOD**

**Restricted benefit**

For use in patients on insulin therapy

**Note**

No applications for increased maximum quantities and/or repeats will be authorised.

### GENERAL NUTRIENTS

### OTHER NUTRIENTS

**TRIGLYCERIDES LONG CHAIN**

**Restricted benefit**

Ketogenic diet

**Clinical criteria:**

- Patient must have intractable seizures requiring treatment with a ketogenic diet; OR
- Patient must have a glucose transport protein defect; OR
- Patient must have pyruvate dehydrogenase deficiency.

Carbzero should only be used under strict supervision of a dietitian, together with a metabolic physician and/or neurologist.

**Note**

Carbzero is not nutritionally complete and is not intended for use as a sole source of nutrition.

**TRIGLYCERIDES MEDIUM CHAIN**

**Authority required**

Chylous ascites

**Authority required**

Chylothorax

**Authority required**

Fat malabsorption due to liver disease, short gut syndrome, cystic fibrosis and gastrointestinal disorders

**Authority required**

Hyperlipoproteinaemia type 1

**Authority required**

Intractable childhood epilepsy or cerebrospinal fluid glucose transporter defect, requiring a ketogenic diet

**Authority required**

Long chain fatty acid oxidation disorders

**Note**

No applications for increased maximum quantities and/or repeats will be authorised.
TRIGLYCERIDES MEDIUM CHAIN

**Authority required**

Ketogenic diet

**Clinical criteria:**
- Patient must have intractable seizures requiring treatment with a ketogenic diet; OR
- Patient must have a glucose transport protein defect; OR
- Patient must have pyruvate dehydrogenase deficiency.

**Authority required**

Dietary management of conditions requiring a source of medium chain triglycerides

**Clinical criteria:**
- Patient must have chylosus ascites; OR
- Patient must have chylothorax; OR
- Patient must have hyperlipoproteinaemia type 1; OR
- Patient must have long chain fatty acid oxidation disorders; OR
- Patient must have fat malabsorption due to liver disease; OR
- Patient must have fat malabsorption due to short gut syndrome; OR
- Patient must have fat malabsorption due to cystic fibrosis; OR
- Patient must have fat malabsorption due to gastrointestinal disorders.

**Note**
No increase in the maximum quantity or number of units may be authorised.

**Note**
No increase in the maximum number of repeats may be authorised.

10049X

triglycerides medium chain oral liquid, 2 5 2 383.86 36.90 betaquik VF

Fat/carbohydrates/proteins/minerals/vitamins, combinations

AMINO ACID SYNTHETIC FORMULA

**Authority required**

Cows' milk protein enteropathy

Treatment Phase: Initial treatment for up to 6 months

**Clinical criteria:**
- The condition must not be isolated infant colic or reflux.
- AND
- Patient must be intolerant to both soy protein and protein hydrolysate formulae, as demonstrated when the child has failed to respond to a strict cows' milk protein free and strict soy protein free diet with a protein hydrolysate (with or without medium chain triglycerides) as the principal formula.

**Population criteria:**
- Patient must be up to the age of 24 months.

**Treatment criteria:**
- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Severe cows' milk protein enteropathy with failure to thrive

Treatment Phase: Initial treatment for up to 6 months

**Clinical criteria:**
- The condition must not be isolated infant colic or reflux.

**Population criteria:**
- Patient must be up to the age of 24 months.

**Treatment criteria:**
- Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a...
specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**
Combined intolerance to cows’ milk protein, soy protein and protein hydrolysate formulae
Treatment Phase: Initial treatment for up to 6 months

**Clinical criteria:**
The condition must not be isolated infant colic or reflux.

**Population criteria:**
Patient must be older than 24 months of age.

**Treatment criteria:**
Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**
Proven combined immunoglobulin E (IgE) mediated allergy to cows’ milk protein and soy protein
Treatment Phase: Initial treatment for up to 6 months

**Clinical criteria:**
Patient must have failed a trial of protein hydrolysate formulae (with or without medium chain triglycerides).

**Population criteria:**
Patient must be up to the age of 24 months.

**Treatment criteria:**
Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Note**
No increase in the maximum quantity or number of units may be authorised.

**Note**
No increase in the maximum number of repeats may be authorised.

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**AMINO ACID SYNTHETIC FORMULA**

**Authority required**
Cows’ milk anaphylaxis

**Population criteria:**
Patient must be up to the age of 24 months.

**Treatment criteria:**
Must be treated by a specialist allergist or clinical immunologist, or in consultation with a specialist allergist or clinical immunologist.

Anaphylaxis is defined as a severe and/or potentially life threatening allergic reaction.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**
Cows’ milk protein enteropathy

Treatment Phase: Continuing treatment
Clinical criteria:
The condition must not be isolated infant colic or reflux.

AND

Patient must be intolerant to both soy protein and protein hydrolysate formulae, as demonstrated when the child has failed to respond to a strict cows' milk protein free and strict soy protein free diet with a protein hydrolysate (with or without medium chain triglycerides) as the principal formula.

Population criteria:
Patient must be up to the age of 24 months.

Treatment criteria:
Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or have an appointment to be assessed by one of these specialists.

The name of the specialist and the date of birth of the patient must be included in the authority application.

Authority required
Severe cows' milk protein enteropathy with failure to thrive
Treatment Phase: Continuing treatment

Clinical criteria:
The condition must not be isolated infant colic or reflux.

AND

Patient must have had failure to thrive prior to commencement with initial treatment.

Population criteria:
Patient must be up to the age of 24 months.

Treatment criteria:
Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or have been assessed at least once or have an appointment to be assessed by one of these specialists.

The name of the specialist and the date of birth of the patient must be included in the authority application.

Authority required
Combined intolerance to cows' milk protein, soy protein and protein hydrolysate formulae
Treatment Phase: Continuing treatment

Clinical criteria:
The condition must not be isolated infant colic or reflux.

Population criteria:
Patient must be older than 24 months of age.

Treatment criteria:
Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist at intervals not greater than 12 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

Authority required
Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein
Treatment Phase: Continuing treatment

Clinical criteria:
Patient must have failed a trial of protein hydrolysate formulae (with or without medium chain triglycerides) prior to commencement with initial treatment.

Population criteria:
Patient must be up to the age of 24 months.

Treatment criteria:
Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

The name of the specialist and the date of birth of the patient must be included in the authority application.
## Authority required

Severe intestinal malabsorption including short bowel syndrome

**Clinical criteria:**

Patient must have failed to respond to protein hydrolysate formulae; OR

Patient must have been receiving parenteral nutrition.

**Note**

Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.

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**AMINO ACID SYNTHETIC FORMULA**

**Authority required**

Eosinophilic oesophagitis

Treatment Phase: Initial treatment for up to 3 months

**Clinical criteria:**

Patient must require an amino acid based formula as a component of a dietary elimination program.

**Population criteria:**

Patient must be 18 years of age or less.

**Treatment criteria:**

Must be treated by a clinical immunologist, suitably qualified allergist or gastroenterologist.

Treatment with oral steroids should not be commenced during the period of initial treatment.

Eosinophilic oesophagitis is demonstrated by the following criteria:

(i) Chronic symptoms of reflux that persisted despite a 2-month trial of a proton pump inhibitor or chronic dysphagia; and

(ii) A lack of demonstrable anatomic abnormality with the exception of stricture, which can be attributable to eosinophilic oesophagitis; and

(iii) Eosinophilic infiltration of the oesophagus, demonstrated by oesophageal biopsy specimens obtained by endoscopy and where the most densely involved oesophageal biopsy had 20 or more eosinophils in any single 400 x high powered field, along with normal antral and duodenal biopsies.

The date of birth of the patient must be included in the authority application.

**Authority required**

Eosinophilic oesophagitis

Treatment Phase: Continuing treatment

**Clinical criteria:**

Patient must have responded to an initial course of PBS-subsidised treatment.

**Population criteria:**

Patient must be 18 years of age or less.

**Treatment criteria:**

Must be treated by a clinical immunologist, suitably qualified allergist or gastroenterologist.

Response to initial treatment is demonstrated by oesophageal biopsy specimens obtained by endoscopy, where the most densely involved oesophageal biopsy had 5 or less eosinophils in any single 400 x high powered field, along with normal antral and duodenal biopsies. The response criteria will not be deemed to have been met if oral steroids were commenced during initial treatment.

**Note**

Authorities for increased maximum quantities, up to a maximum of 52, may be authorised.
VARIOUS

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AMINO ACID SYNTHETIC FORMULA SUPPLEMENTED WITH LONG CHAIN POLYUNSATURATED FATTY ACIDS

**Authority required**

Cows' milk protein enteropathy

Treatment Phase: Initial treatment for up to 6 months

**Clinical criteria:**

The condition must not be isolated infant colic or reflux,

AND

Patient must be intolerant to both soy protein and protein hydrolysate formulae, as demonstrated when the child has failed to respond to a strict cows' milk protein free and strict soy protein free diet with a protein hydrolysate (with or without medium chain triglycerides) as the principal formula.

**Population criteria:**

Patient must be up to the age of 24 months.

**Treatment criteria:**

Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Severe cows' milk protein enteropathy with failure to thrive

Treatment Phase: Initial treatment for up to 6 months

**Clinical criteria:**

The condition must not be isolated infant colic or reflux.

**Population criteria:**

Patient must be up to the age of 24 months.

**Treatment criteria:**

Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Combined intolerance to cows' milk protein, soy protein and protein hydrolysate formulae

Treatment Phase: Initial treatment for up to 6 months

**Clinical criteria:**

The condition must not be isolated infant colic or reflux.

**Population criteria:**

Patient must be older than 24 months of age.

**Treatment criteria:**

Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein

Treatment Phase: Initial treatment for up to 6 months

**Clinical criteria:**

Patient must have failed a trial of protein hydrolysate formulae (with or without medium chain triglycerides).

**Population criteria:**

Patient must be up to the age of 24 months.
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**AMINO ACID SYNTHETIC FORMULA SUPPLEMENTED WITH LONG CHAIN POLYUNSATURATED FATTY ACIDS**

**Authority required**

Cows’ milk anaphylaxis

**Population criteria:**
Patient must be up to the age of 24 months.

**Treatment criteria:**
Must be treated by a specialist allergist or clinical immunologist, or in consultation with a specialist allergist or clinical immunologist.

Anaphylaxis is defined as a severe and/or potentially life threatening allergic reaction.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Cows’ milk protein enteropathy

**Treatment Phase:** Continuing treatment

**Clinical criteria:**
The condition must not be isolated infant colic or reflux,

AND

Patient must be intolerant to both soy protein and protein hydrolysate formulae, as demonstrated when the child has failed to respond to a strict cows’ milk protein free and strict soy protein free diet with a protein hydrolysate (with or without medium chain triglycerides) as the principal formula.

**Population criteria:**
Patient must be up to the age of 24 months.

**Treatment criteria:**
Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or have an appointment to be assessed by one of these specialists.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Severe cows’ milk protein enteropathy with failure to thrive

**Treatment Phase:** Continuing treatment

**Clinical criteria:**
The condition must not be isolated infant colic or reflux,

AND

Patient must have had failure to thrive prior to commencement with initial treatment.

**Population criteria:**
**VARIOUS**

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<td>Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein</td>
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<td></td>
<td>Patient must have failed to respond to protein hydrolysate formulae; OR</td>
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<td>Patient must have been receiving parenteral nutrition.</td>
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<td>Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.</td>
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![AMINO ACID SYNTHETIC FORMULA SUPPLEMENTED WITH LONG CHAIN POLYUNSATURATED FATTY ACIDS AND MEDIUM CHAIN TRIGLYCERIDES](attachment:aminoacid.png)

**Authority required**

Eosinophilic oesophagitis

Treatment Phase: Initial treatment for up to 3 months
<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
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<tr>
<td>1545H</td>
<td>amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids and medium chain triglycerides oral liquid: powder for, 400 g</td>
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<td>*542.56</td>
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</table>

**Clinical criteria:**
Patient must require an amino acid based formula as a component of a dietary elimination program.

**Population criteria:**
Patient must be 18 years of age or less.

**Treatment criteria:**
Must be treated by a clinical immunologist, suitably qualified allergist or gastroenterologist.

Treatment with oral steroids should not be commenced during the period of initial treatment.

Eosinophilic oesophagitis is demonstrated by the following criteria:
(i) Chronic symptoms of reflux that persisted despite a 2-month trial of a proton pump inhibitor or chronic dysphagia; and
(ii) A lack of demonstrable anatomic abnormality with the exception of stricture, which can be attributable to eosinophilic oesophagitis; and
(iii) Eosinophilic infiltration of the oesophagus, demonstrated by oesophageal biopsy specimens obtained by endoscopy and where the most densely involved oesophageal biopsy had 20 or more eosinophils in any single 400 x high powered field, along with normal antral and duodenal biopsies.

The date of birth of the patient must be included in the authority application.

**Authority required**
Eosinophilic oesophagitis

Treatment Phase: Continuing treatment

**Clinical criteria:**
Patient must have responded to an initial course of PBS-subsidised treatment.

**Population criteria:**
Patient must be 18 years of age or less.

**Treatment criteria:**
Must be treated by a clinical immunologist, suitably qualified allergist or gastroenterologist.

Response to initial treatment is demonstrated by oesophageal biopsy specimens obtained by endoscopy, where the most densely involved oesophageal biopsy had 5 or less eosinophils in any single 400 x high powered field, along with normal antral and duodenal biopsies. The response criteria will not be deemed to have been met if oral steroids were commenced during initial treatment.

**Note**
Authorities for increased maximum quantities, up to a maximum of 52, may be authorised.
to be assessed by one of these specialists.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**
Severe cows' milk protein enteropathy with failure to thrive
Treatment Phase: Continuing treatment

**Clinical criteria:**
The condition must not be isolated infant colic or reflux,
AND
Patient must have had failure to thrive prior to commencement with initial treatment.

**Population criteria:**
Patient must be up to the age of 24 months.

**Treatment criteria:**
Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or have been assessed at least once or have an appointment to be assessed by one of these specialists.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**
Combined intolerance to cows’ milk protein, soy protein and protein hydrolysate formulae
Treatment Phase: Continuing treatment

**Clinical criteria:**
The condition must not be isolated infant colic or reflux.

**Population criteria:**
Patient must be older than 24 months of age.

**Treatment criteria:**
Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist at intervals not greater than 12 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**
Cows’ milk anaphylaxis

**Population criteria:**
Patient must be up to the age of 24 months.

**Treatment criteria:**
Must be treated by a specialist allergist or clinical immunologist, or in consultation with a specialist allergist or clinical immunologist.

Anaphylaxis is defined as a severe and/or potentially life threatening allergic reaction.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**
Proven combined immunoglobulin E (IgE) mediated allergy to cows’ milk protein and soy protein
Treatment Phase: Continuing treatment

**Clinical criteria:**
Patient must have failed a trial of protein hydrolysate formulae (with or without medium chain triglycerides) prior to commencement with initial treatment.

**Population criteria:**
Patient must be up to the age of 24 months.

**Treatment criteria:**
Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.
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<tr>
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**Note**

Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.

2900P NP

### AMINO ACID SYNTHETIC FORMULA SUPPLEMENTED WITH LONG CHAIN POLYUNSATURATED FATTY ACIDS AND MEDIUM CHAIN TRIGLYCERIDES

**Authority required**

Cows’ milk protein enteropathy

Treatment Phase: Initial treatment for up to 6 months

**Clinical criteria:**

The condition must not be isolated infant colic or reflux,

**AND**

Patient must be intolerant to both soy protein and protein hydrolysate formulae, as demonstrated when the child has failed to respond to a strict cows’ milk protein free and strict soy protein free diet with a protein hydrolysate (with or without medium chain triglycerides) as the principal formula.

**Population criteria:**

Patient must be up to the age of 24 months.

**Treatment criteria:**

Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Severe cows’ milk protein enteropathy with failure to thrive

Treatment Phase: Initial treatment for up to 6 months

**Clinical criteria:**

The condition must not be isolated infant colic or reflux.

**Population criteria:**

Patient must be up to the age of 24 months.

**Treatment criteria:**

Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Combined intolerance to cows’ milk protein, soy protein and protein hydrolysate formulae

Treatment Phase: Initial treatment for up to 6 months

**Clinical criteria:**

The condition must not be isolated infant colic or reflux.

**Population criteria:**

Patient must be older than 24 months of age.

**Treatment criteria:**

Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

The name of the specialist and the date of birth of the patient must be included in the authority application.
### Authority required
Proven combined immunoglobulin E (IgE) mediated allergy to cows’ milk protein and soy protein

**Clinical criteria:**
Patient must have failed a trial of protein hydrolysate formulae (with or without medium chain triglycerides).

**Population criteria:**
Patient must be up to the age of 24 months.

**Treatment criteria:**
Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

The name of the specialist and the date of birth of the patient must be included in the authority application.

### Note
No increase in the maximum quantity or number of units may be authorised.

### Note
No increase in the maximum number of repeats may be authorised.

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**AMINO ACID SYNTHETIC FORMULA SUPPLEMENTED WITH LONG CHAIN POLYUNSATURATED FATTY ACIDS AND MEDIUM CHAIN TRIGLYCERIDES**

### Authority required
Cows’ milk anaphylaxis

**Population criteria:**
Patient must be up to the age of 24 months.

**Treatment criteria:**
Must be treated by a specialist allergist or clinical immunologist, or in consultation with a specialist allergist or clinical immunologist.

Anaphylaxis is defined as a severe and/or potentially life threatening allergic reaction.

The name of the specialist and the date of birth of the patient must be included in the authority application.

### Authority required
Cows’ milk protein enteropathy

**Clinical criteria:**
The condition must not be isolated infant colic or reflux.

**AND**
Patient must be intolerant to both soy protein and protein hydrolysate formulae, as demonstrated when the child has failed to respond to a strict cows’ milk protein free and strict soy protein free diet with a protein hydrolysate (with or without medium chain triglycerides) as the principal formula.

**Population criteria:**
Patient must be up to the age of 24 months.

**Treatment criteria:**
Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or have an appointment to be assessed by one of these specialists.
The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**
Severe cows’ milk protein enteropathy with failure to thrive
Treatment Phase: Continuing treatment

**Clinical criteria:**
The condition must not be isolated infant colic or reflux,

**AND**
Patient must have had failure to thrive prior to commencement with initial treatment.

**Population criteria:**
Patient must be up to the age of 24 months.

**Treatment criteria:**
Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or have been assessed at least once or have an appointment to be assessed by one of these specialists.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**
Combined intolerance to cows’ milk protein, soy protein and protein hydrolysate formulae
Treatment Phase: Continuing treatment

**Clinical criteria:**
The condition must not be isolated infant colic or reflux.

**Population criteria:**
Patient must be older than 24 months of age.

**Treatment criteria:**
Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist at intervals not greater than 12 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**
Proven combined immunoglobulin E (IgE) mediated allergy to cows’ milk protein and soy protein
Treatment Phase: Continuing treatment

**Clinical criteria:**
Patient must have failed a trial of protein hydrolysate formulae (with or without medium chain triglycerides) prior to commencement with initial treatment.

**Population criteria:**
Patient must be up to the age of 24 months.

**Treatment criteria:**
Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**
Severe intestinal malabsorption including short bowel syndrome

**Clinical criteria:**
Patient must have failed to respond to protein hydrolysate formulae; OR
Patient must have been receiving parenteral nutrition.

**Note**
Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.
supplemented with long chain polyunsaturated fatty acids and medium chain triglycerides oral liquid: powder for, 400 g

**PROTEIN HYDROLYSATE FORMULA WITH MEDIUM CHAIN TRIGLYCERIDES**

**Authority required**

Cows’ milk protein enteropathy and intolerance to soy protein

Treatment Phase: Initial treatment

**Clinical criteria:**

The condition must not be isolated infant colic or reflux,

AND

Patient must have failed to respond to a strict soy-based cows’ milk protein free diet.

**Population criteria:**

Patient must be up to the age of 24 months.

**Treatment criteria:**

Must be treated by a specialist allergist, clinical immunologist, specialist paediatrician or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist, specialist paediatrician or specialist paediatric gastroenterologist and hepatologist.

The date of birth of the patient must be included in the authority application.

**Authority required**

Cows’ milk protein enteropathy and intolerance to soy protein

Treatment Phase: Continuing treatment

**Clinical criteria:**

The condition must not be isolated infant colic or reflux,

AND

Patient must have demonstrated a clinical improvement with the protein hydrolysate formula with medium chain triglycerides.

**Population criteria:**

Patient must be up to the age of 24 months.

**Treatment criteria:**

Must be treated by a specialist allergist, clinical immunologist, specialist paediatrician or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist, specialist paediatrician or specialist paediatric gastroenterologist and hepatologist.

The date of birth of the patient must be included in the authority application.

**Authority required**

Cows’ milk protein enteropathy and intolerance to soy protein

Clinical criteria:

The condition must not be isolated infant colic or reflux,

AND

Patient must have failed to respond to a strict soy-based cows’ milk protein free diet.

**Population criteria:**

Patient must be older than 24 months of age.

**Treatment criteria:**

Must be treated by a specialist allergist, clinical immunologist, specialist paediatrician or specialist paediatric gastroenterologist and hepatologist.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Proven combined immunoglobulin E (IgE) mediated allergy to cows’ milk protein and soy protein

Treatment Phase: Initial treatment for up to 6 months

**Population criteria:**

Patient must be up to the age of 24 months.
Treatment criteria:
Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**
Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein
Treatment Phase: Continuing treatment

**Population criteria:**
Patient must be up to the age of 24 months.

**Treatment criteria:**
Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**
Biliary atresia

**Authority required**
Chronic liver failure with fat malabsorption

**Authority required**
Chylous ascites

**Authority required**
Cystic fibrosis

**Authority required**
Enterokinase deficiency

**Authority required**
Proven fat malabsorption

**Authority required**
Severe diarrhoea of greater than 2 weeks duration

**Population criteria:**
Patient must be aged less than 4 months.

The date of birth of the patient must be included in the authority application.

**Authority required**
Severe intestinal malabsorption including short bowel syndrome

**Authority required**
Chylothorax

**Note**
No increase in the maximum quantity or number of units may be authorised.

**Note**
No increase in the maximum number of repeats may be authorised.

**2676W**

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**PROTEIN HYDROLYSATE FORMULA WITH MEDIUM CHAIN TRIGLYCERIDES**

**Authority required**
Cows' milk protein enteropathy and intolerance to soy protein
Treatment Phase: Initial treatment

**Clinical criteria:**
The condition must not be isolated infant colic or reflux,

**AND**
Patient must have failed to respond to a strict soy-based cows' milk protein free diet.
**Population criteria:**
Patient must be up to the age of 24 months.

**Treatment criteria:**
Must be treated by a specialist allergist, clinical immunologist, specialist paediatrician or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist, specialist paediatrician or specialist paediatric gastroenterologist and hepatologist.

The date of birth of the patient must be included in the authority application.

**Authority required**
Cows’ milk protein enteropathy and intolerance to soy protein
Treatment Phase: Continuing treatment

**Clinical criteria:**
The condition must not be isolated infant colic or reflux,
AND
Patient must have demonstrated a clinical improvement with the protein hydrolysate formula with medium chain triglycerides.

**Population criteria:**
Patient must be up to the age of 24 months.

**Treatment criteria:**
Must be treated by a specialist allergist, clinical immunologist, specialist paediatrician or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist, specialist paediatrician or specialist paediatric gastroenterologist and hepatologist.

The date of birth of the patient must be included in the authority application.

**Authority required**
Proven combined immunoglobulin E (IgE) mediated allergy to cows’ milk protein and soy protein
Treatment Phase: Initial treatment for up to 6 months

**Population criteria:**
Patient must be up to the age of 24 months.

**Treatment criteria:**
Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**
Proven combined immunoglobulin E (IgE) mediated allergy to cows’ milk protein and soy protein
Treatment Phase: Continuing treatment

**Population criteria:**
Patient must be up to the age of 24 months.

**Treatment criteria:**
Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**
Biliary atresia

**Authority required**
Chronic liver failure with fat malabsorption

**Authority required**
Chylous ascites

**Authority required**
Cystic fibrosis

**Authority required**
Enterokinase deficiency

**Authority required**
Proven fat malabsorption

**Authority required**
Severe diarrhoea of greater than 2 weeks duration

**Population criteria:**
Patient must be aged less than 4 months.

The date of birth of the patient must be included in the authority application.

**Authority required**
Severe intestinal malabsorption including short bowel syndrome

**Note**
No increase in the maximum quantity or number of units may be authorised.

**Note**
No increase in the maximum number of repeats may be authorised.

**TRIGLYCERIDES MEDIUM CHAIN FORMULA**

**Restricted benefit**
Fat malabsorption due to liver disease, short gut syndrome, cystic fibrosis and gastrointestinal disorders

**Restricted benefit**
Hyperlipoproteinaemia type 1

**Restricted benefit**
Long chain fatty acid oxidation disorders

**Restricted benefit**
Chylous ascites

**Restricted benefit**
Chylothorax

**Note**
No applications for increased maximum quantities and/or repeats will be authorised.

**Note**
Not indicated for the treatment of intractable childhood epilepsy or cerebrospinal fluid glucose transporter defect requiring a ketogenic diet.

**Carbohydrates**

**AMYLOPECTIN MODIFIED LONG CHAIN**

**Restricted benefit**
Glycogen storage disease

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
<th>Premium $ for Max. Qty</th>
<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>8259Q</td>
<td>protein hydrolysate formula with medium chain triglycerides oral liquid: powder for, 450 g</td>
<td>8</td>
<td>5</td>
<td>*110.20</td>
<td>36.90</td>
<td>Karicare Aptamil Pepti-Junior Gold NU</td>
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<tr>
<td>1938B</td>
<td>triglycerides medium chain formula oral liquid: powder for, 400 g</td>
<td>8</td>
<td>5</td>
<td>*443.16</td>
<td>36.90</td>
<td>Lipistart VF</td>
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<tr>
<td>8478F</td>
<td>triglycerides medium chain formula oral liquid: powder for, 400 g</td>
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<td>5</td>
<td>*421.64</td>
<td>36.90</td>
<td>Monogen SB</td>
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<tr>
<td>9386B</td>
<td>amylopectin modified long chain oral</td>
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<td>5</td>
<td>*752.64</td>
<td>36.90</td>
<td>Glycosade VF</td>
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### Milk substitutes

**MILK POWDER LACTOSE FREE FORMULA**

**Authority required**

Acute lactose intolerance in infants up to the age of 12 months. The date of birth of the patient must be included in the authority application.

**Note**

No applications for increased maximum quantities and/or repeats will be authorised. No more than 1 application per patient will be authorised.

<table>
<thead>
<tr>
<th>Code</th>
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<td>NP</td>
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<table>
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<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>8282X</td>
<td>milk powder lactose free formula oral liquid: powder for, 900 g</td>
<td>5</td>
<td></td>
<td></td>
<td>*113.21</td>
<td>36.90</td>
<td>S-26 LF</td>
</tr>
<tr>
<td>NP</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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</table>

**MILK POWDER LACTOSE FREE FORMULA**

**Authority required**

Proven chronic lactose intolerance in infants up to the age of 12 months. The date of birth of the patient must be included in the authority application. Lactose intolerance must have been proven by either:

(a) relief of symptoms on supervised withdrawal of lactose from the diet for 3 or 4 days and subsequent re-emergence of symptoms on rechallenge with lactose containing formulae or milk or food; or

(b) not less than 0.5% reducing substance in stool exudate tested with copper sulfate diagnostic compound tablet; or

(c) hydrogen breath test

**Note**

No applications for increased maximum quantities and/or repeats will be authorised.

<table>
<thead>
<tr>
<th>Code</th>
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<td>36.90</td>
<td>S-26 LF</td>
</tr>
<tr>
<td>NP</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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**MILK POWDER LACTOSE FREE FORMULA PREDIGESTED**

**Authority required**

Acute lactose intolerance

**Population criteria:**

Patient must be up to the age of 12 months.

The date of birth of the patient must be included in the authority application.

**Note**

No increase in the maximum quantity or number of units may be authorised.

**Note**

No increase in the maximum number of repeats may be authorised.

**Note**

No more than 1 application per patient will be authorised.

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<tr>
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<tr>
<td>2975N</td>
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<td>36.90</td>
<td>Karicare Aptamil Gold De-Lact</td>
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<td>NP</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>NU</td>
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</table>

**MILK POWDER LACTOSE FREE FORMULA PREDIGESTED**

**Authority required**

Chronic lactose intolerance

**Clinical criteria:**

The condition must be proven to be lactose intolerance.

**Population criteria:**

Patient must be up to the age of 12 months.

Lactose intolerance must have been proven by either:

(a) relief of symptoms on supervised withdrawal of lactose from the diet for 3 or 4 days and subsequent re-emergence of symptoms on rechallenge with lactose containing formulae or milk or food; or

(b) not less than 0.5% reducing substance in stool exudate tested with copper sulfate diagnostic compound tablet; or

(c) hydrogen breath test.

The date of birth of the patient must be included in the authority application.
<table>
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<tr>
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<td>5</td>
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<td>Karicare Aptamil Gold De-Lact NU</td>
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<tr>
<td>2357C</td>
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<td>2358D</td>
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<td>1</td>
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<td>36.90</td>
<td>Digestelact SJ</td>
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<tr>
<td>3092R</td>
<td>milk powder synthetic low calcium oral liquid: powder for, 400 g</td>
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<td>5</td>
<td>*381.72</td>
<td>36.90</td>
<td>Locasol SB</td>
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</tbody>
</table>

**Other combinations of nutrients**

**AMINO ACID FORMULA WITH FAT, CARBOHYDRATE, VITAMINS, MINERALS AND TRACE ELEMENTS WITHOUT METHIONINE AND SUPPLEMENTED WITH DOCOSAHEXAENOIC ACID**

Restricted benefit
Pyridoxine non-responsive homocystinuria

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
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<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>3417W</td>
<td>amino acid formula with fat, carbohydrate, vitamins, minerals and trace elements without methionine and supplemented with docosahexaenoic acid oral liquid, 36 x 125 mL cans</td>
<td>4</td>
<td>5</td>
<td>*2508.32</td>
<td>36.90</td>
<td>HCU Anamix junior LQ SB</td>
</tr>
</tbody>
</table>

**AMINO ACID FORMULA WITH FAT, CARBOHYDRATE, VITAMINS, MINERALS AND TRACE ELEMENTS WITHOUT PHENYLALANINE AND TYROSINE, AND SUPPLEMENTED WITH DOCOSAHEXAENOIC ACID**

Restricted benefit
Tyrosinaemia

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
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</thead>
<tbody>
<tr>
<td>9330C</td>
<td>amino acid formula with fat, carbohydrate, vitamins, minerals and trace elements without phenylalanine and tyrosine, and supplemented with docosahexaenoic acid oral liquid, 36 x 125 mL cans</td>
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<td>5</td>
<td>*2508.32</td>
<td>36.90</td>
<td>TYR Anamix junior LQ SB</td>
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**AMINO ACID FORMULA WITHOUT PHENYLALANINE**

Restricted benefit
<table>
<thead>
<tr>
<th>Code</th>
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<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>8678R 8678R NP</td>
<td>amino acid formula without phenylalanine 1 g tablet, 75</td>
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<td>5</td>
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<td>Phlexy-10</td>
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<tr>
<td>8554F 8554F NP</td>
<td>amino acid formula without phenylalanine 500 mg capsule, 200</td>
<td>16</td>
<td>5</td>
<td>*1276.68</td>
<td>36.90</td>
<td>Phlexy-10</td>
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<td>2347M 2347M NP</td>
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<td>5</td>
<td>*1463.25</td>
<td>36.90</td>
<td>Phlexy-10 Drink Mix</td>
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<td>8479G 8479G NP</td>
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<td>5</td>
<td>*703.96</td>
<td>36.90</td>
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<td>9438R 9438R NP</td>
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<td>36.90</td>
<td>GA gel</td>
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<td>5484P 5484P NP</td>
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<td>5</td>
<td>*3154.76</td>
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<tr>
<td>2650L 2650L NP</td>
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<td>5</td>
<td>*769.64</td>
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<td>GA1 Anamix infant</td>
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<tr>
<td>2646G 2646G NP</td>
<td>amino acid formula with vitamins and minerals without lysine and low in tryptophan oral liquid: powder for, 500 g</td>
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<td>5</td>
<td>*1785.08</td>
<td>36.90</td>
<td>XLYS, LOW TRY Maxamaid</td>
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<tr>
<td>1548L 1548L NP</td>
<td>AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT METHIONINE Oral liquid 125 mL, 30, 1</td>
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<td>5</td>
<td>*3098.68</td>
<td>36.90</td>
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<tr>
<td>9133Q 9133Q NP</td>
<td>amino acid formula with vitamins and minerals without methionine oral liquid, 30 x 130 mL cans</td>
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<td>5</td>
<td>*3098.72</td>
<td>36.90</td>
<td>HCU cooler 15</td>
</tr>
<tr>
<td>2640Y 2640Y NP</td>
<td>amino acid formula with vitamins and minerals without methionine oral liquid, 30 x 174 mL pouches</td>
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<td>5</td>
<td>*4082.72</td>
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<td>HCU cooler 20</td>
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<tr>
<td>2639X 2639X NP</td>
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<td>8677Q 8677Q NP</td>
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<td>5</td>
<td>*2114.72</td>
<td>36.90</td>
<td>HCU gel</td>
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</table>

**Phenylketonuria**

**AMINO ACID FORMULA WITH VITAMINS, MINERALS AND LONG CHAIN POLYUNSATURATED FATTY ACIDS WITHOUT PHENYLALANINE**

**Restricted benefit**

Phenylketonuria

**AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT LYSINE AND LOW IN TRYPTOPHAN**

**Restricted benefit**

A child aged from 6 months up to 10 years with proven glutaric aciduria type 1

**AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT LYSINE AND LOW IN TRYPTOPHAN**

**Restricted benefit**

A patient aged 3 years or older with proven glutaric aciduria type 1

**AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT LYSINE AND LOW IN TRYPTOPHAN**

**Restricted benefit**

A child aged less than 9 years with proven glutaric aciduria type 1

**AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT METHIONINE**

**Restricted benefit**

Pyridoxine non-responsive homocystinuria
<table>
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<tbody>
<tr>
<td>NP</td>
<td>minerals without methionine oral liquid: powder for, 30 x 24 g sachets amino acid formula with vitamins and minerals without methionine oral liquid: powder for, 30 x 25 g sachets</td>
<td>4 5</td>
<td>...</td>
<td>*3098.72</td>
<td>36.90</td>
<td>HCU express 15</td>
<td>VF</td>
</tr>
<tr>
<td>NP</td>
<td>amino acid formula with vitamins and minerals without methionine oral liquid: powder for, 500 g</td>
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<td>...</td>
<td>*1785.08</td>
<td>36.90</td>
<td>XMET Maxamaid</td>
<td>SB</td>
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<td>NP</td>
<td>amino acid formula with vitamins and minerals without methionine oral liquid: powder for, 400 g</td>
<td>8 5</td>
<td>...</td>
<td>*2705.08</td>
<td>36.90</td>
<td>XMET Maxamum</td>
<td>SB</td>
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<td>36.90</td>
<td>Easiphen</td>
<td>SB</td>
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<tr>
<td>NP</td>
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<td>1549.78</td>
<td>36.90</td>
<td>PKU Lophlex LQ 20</td>
<td>SB</td>
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<tr>
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<td>36.90</td>
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<td>1058.96</td>
<td>36.90</td>
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<td>5</td>
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<td>1035.12</td>
<td>36.90</td>
<td>PKU Cooler 10</td>
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<td>5</td>
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<td>1270.20</td>
<td>36.90</td>
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<td>5</td>
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<td>1058.96</td>
<td>36.90</td>
<td>PKU Anamix Junior</td>
</tr>
<tr>
<td>NP</td>
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<td>1549.48</td>
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<td>5</td>
<td>...</td>
<td>1549.78</td>
<td>36.90</td>
<td>PKU express 15</td>
</tr>
<tr>
<td>NP</td>
<td>amino acid formula with vitamins and minerals without phenylalanine oral liquid: powder for, 30 x 27.8 g sachets</td>
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<td>5</td>
<td>...</td>
<td>1512.40</td>
<td>36.90</td>
<td>PKU Anamix Junior</td>
</tr>
<tr>
<td>NP</td>
<td>amino acid formula with vitamins and minerals without phenylalanine oral liquid: powder for, 30 x 29 g sachets</td>
<td>3</td>
<td>5</td>
<td>...</td>
<td>1512.40</td>
<td>36.90</td>
<td>XP Maxamum 20</td>
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<tr>
<td>NP</td>
<td>amino acid formula with vitamins and minerals without phenylalanine oral liquid: powder for, 30 x 50 g sachets</td>
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<td>5</td>
<td>...</td>
<td>884.36</td>
<td>36.90</td>
<td>XP Maxamaid</td>
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<tr>
<td>NP</td>
<td>amino acid formula with vitamins and minerals without phenylalanine oral liquid: powder for, 500 g</td>
<td>8</td>
<td>5</td>
<td>...</td>
<td>1352.76</td>
<td>36.90</td>
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<td>NP</td>
<td>amino acid formula with vitamins and minerals without phenylalanine oral semi-solid, 36 x 109 g jars</td>
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<td>5</td>
<td>...</td>
<td>1853.08</td>
<td>36.90</td>
<td>PKU Lophlex Sensation 20</td>
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</tbody>
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**AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT PHENYLALANINE AND TYROSINE**

**Restricted benefit**

Tyrosinaemia

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>Dispensed Price for Max. Qty $</th>
<th>Maximum Recordable Value for Safety Net $</th>
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<td>AMINO ACID FORMULA WITH VITAMINS and MINERALS without PHENYLALANINE and TYROSINE Oral liquid 125 mL, 30, 1</td>
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<td>5</td>
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<td>36.90</td>
<td>TYR Lophlex LQ 20</td>
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<tr>
<td>NP</td>
<td>amino acid formula with vitamins and minerals without phenylalanine and tyrosine oral liquid, 30 x 130 mL cans</td>
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<td>3098.72</td>
<td>36.90</td>
<td>TYR cooler 15</td>
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<tr>
<td>NP</td>
<td>amino acid formula with vitamins and minerals without phenylalanine and tyrosine oral liquid, 30 x 174 mL pouches</td>
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<td>*769.64</td>
<td>36.90</td>
<td>TYR Anamix infant SB</td>
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<td>3078B</td>
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<td>XPhen, Tyr Maxamum SB</td>
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<td>amino acid formula with vitamins and minerals without phenylalanine and tyrosine oral liquid: powder for, 500 g</td>
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<td>5</td>
<td>..</td>
<td>*1785.08</td>
<td>36.90</td>
<td>XPhen, Tyr Maxamaid SB</td>
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**AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT VALINE, LEUCINE AND ISOLEUCINE**

**Restricted benefit**

Maple syrup urine disease

<table>
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<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>Dispensed Price for Max. Qty $</th>
<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
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<tr>
<td>1546J</td>
<td>AMINO ACID FORMULA WITH VITAMINS and MINERALS without VALINE, LEUCINE and ISOLEUCINE Oral liquid 125 mL, 30, 1 sachets</td>
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<td>5</td>
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<td>36.90</td>
<td>MSUD Lophlex LQ 20 SB</td>
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<td>1914R</td>
<td>AMINO ACID FORMULA WITH VITAMINS and MINERALS without VALINE, LEUCINE and ISOLEUCINE Sachets 34 g, 30, 1 Sachets</td>
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<td>5</td>
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<td>2375B</td>
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<td>*3098.72</td>
<td>36.90</td>
<td>MSUD cooler 15 VF</td>
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<tr>
<td>2654Q</td>
<td>amino acid formula with vitamins and minerals without valine, leucine and isoleucine oral liquid, 30 x 174 mL pouches</td>
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<td>amino acid formula with vitamins and minerals without valine, leucine and isoleucine oral liquid: powder for, 30 x 24 g sachets</td>
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<td>8632H</td>
<td>amino acid formula with vitamins and minerals without valine, leucine and isoleucine oral liquid: powder for, 30 x 25 g sachets</td>
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<td>amino acid formula with vitamins and minerals without valine, leucine and isoleucine oral liquid: powder for, 30 x 29 g sachets</td>
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<td>36.90</td>
<td>MSUD Anamix Junior SB</td>
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<td>2380G</td>
<td>amino acid formula with vitamins and minerals without valine, leucine and isoleucine oral liquid: powder for, 400 g</td>
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<td>5</td>
<td>..</td>
<td>*2672.32</td>
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<td>MSUD AID III SB</td>
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</table>

**AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT VALINE, LEUCINE AND ISOLEUCINE WITH FAT, CARBOHYDRATE AND TRACE ELEMENTS AND SUPPLEMENTED WITH DOCOSAHEXAENOIC ACID**

**Restricted benefit**
<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
<th>Dispensed Price for Max. Qty $</th>
<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>9499Y</td>
<td>Maple syrup urine disease amino acid formula with vitamins and minerals without valine, leucine and isoleucine with fat, carbohydrate and trace elements and supplemented with docosahexaenoic acid oral liquid, 36 cans</td>
<td>4</td>
<td>5</td>
<td>*2508.32</td>
<td>36.90</td>
<td>MSUD Anamix Junior LQ</td>
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<tr>
<td>10036F</td>
<td>ARACHIDONIC ACID AND DOCOSAHEXAENOIC ACID WITH CARBOHYDRATE Authority required</td>
<td>4</td>
<td>5</td>
<td>*371.16</td>
<td>36.90</td>
<td>keyomega</td>
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<tr>
<td>5482M</td>
<td>arginine with carbohydrate containing 2 g arginine oral liquid: powder for, 30 x 4 g sachets</td>
<td>4</td>
<td>5</td>
<td>*771.16</td>
<td>36.90</td>
<td>Arginine 2000</td>
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<tr>
<td>10093F</td>
<td>arginine with carbohydrate containing 5 g arginine oral liquid: powder for, 30 x 7.6 g sachets</td>
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<td>*1023.44</td>
<td>36.90</td>
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<td>9437Q</td>
<td>arginine with carbohydrate containing 500 mg arginine oral liquid: powder for, 30 x 4 g sachets</td>
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<td>5</td>
<td>*516.36</td>
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<td>Arginine 500</td>
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<tr>
<td>8369L</td>
<td>CARBOHYDRATE, FAT, VITAMINS, MINERALS AND TRACE ELEMENTS Restricted benefit Proven inborn errors of protein metabolism</td>
<td>8</td>
<td>5</td>
<td>*318.52</td>
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<td>Energivit</td>
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<td>10050Y</td>
<td>CARBOHYDRATES, FAT, VITAMINS, MINERALS, TRACE ELEMENTS AND SUPPLEMENTED WITH ARACHIDONIC ACID AND DOCOSAHEXAENOIC ACID Restricted benefit Proven inborn errors of protein metabolism</td>
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<td>*248.60</td>
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<td>10039J</td>
<td>CARBOHYDRATES, FAT, VITAMINS, MINERALS, TRACE ELEMENTS AND SUPPLEMENTED WITH ARACHIDONIC ACID AND DOCOSAHEXAENOIC ACID Restricted benefit Proven inborn errors of protein metabolism</td>
<td>4</td>
<td>5</td>
<td>*472.48</td>
<td>36.90</td>
<td>basecal 200</td>
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<td>596</td>
<td>CITRULLINE WITH CARBOHYDRATE Restricted benefit Urea cycle disorders in order to prevent low plasma arginine or citrulline levels</td>
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**Note:**
- Citrulline with carbohydrate is not indicated for the treatment of arginase deficiency and other inborn errors of protein metabolism.
- Arginine with carbohydrate is not indicated for the treatment of arginase deficiency and other inborn errors of protein metabolism.
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<td>Pyridoxine non-responsive homocystinuria</td>
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<td>docosahexaenoic acid with carbohydrate containing 200 mg docosahexaenoic acid oral liquid: powder for, 30 x 4 g sachets</td>
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<td><strong>GLYCOMACROPEPTIDE AND ESSENTIAL AMINO ACIDS</strong></td>
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<td>2712R</td>
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<tr>
<td>2696K</td>
<td>glycomacropeptide and essential amino acids with vitamins and minerals bar, 7 x 54 g</td>
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<td>5</td>
<td>..</td>
<td>*866.78</td>
<td>36.90</td>
<td>Camino Pro Complete QH</td>
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<tr>
<td>2644E</td>
<td>glycomacropeptide and essential amino acids with vitamins and minerals bar, 7 x 81 g</td>
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<td>36.90</td>
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<td>2685H</td>
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<td>5</td>
<td>..</td>
<td>*1480.12</td>
<td>36.90</td>
<td>Camino Pro Bettermilk QH</td>
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</tbody>
</table>

**HIGH FAT FORMULA WITH VITAMINS, MINERALS AND TRACE ELEMENTS AND LOW IN PROTEIN AND CARBOHYDRATE**
### Restricted benefit

**Ketogenic diet**

**Clinical criteria:**

- Patient must have intractable seizures requiring treatment with a ketogenic diet; OR
- Patient must have a glucose transport protein defect; OR
- Patient must have pyruvate dehydrogenase deficiency.

KetoCal 3:1 should only be used under strict supervision of a dietitian, together with a metabolic physician and/or neurologist.

**Note**

Authorities for increased maximum quantities, up to a maximum of 48, may be authorised.

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<thead>
<tr>
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<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>2652N</td>
<td>high fat formula with vitamins, minerals and trace elements and low in protein and carbohydrate (3:1 ratio long chain fat to carbohydrate plus protein) oral liquid: powder for, 300 g</td>
<td>24</td>
<td>5</td>
<td>..</td>
<td>*1037.80</td>
<td>36.90</td>
</tr>
</tbody>
</table>

**HIGH FAT FORMULA WITH VITAMINS, MINERALS AND TRACE ELEMENTS AND LOW IN PROTEIN AND CARBOHYDRATE**

### Restricted benefit

**Ketogenic diet**

**Clinical criteria:**

- Patient must have intractable seizures requiring treatment with a ketogenic diet; OR
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KetoCal 4:1 should only be used under strict supervision of a dietitian, together with a metabolic physician and/or neurologist.

**Note**

Authorities for increased maximum quantities, up to a maximum of 48, may be authorised.

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<thead>
<tr>
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<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>9446E</td>
<td>high fat formula with vitamins, minerals and trace elements and low in protein and carbohydrate (4:1 ratio long chain fat to carbohydrate plus protein) oral liquid: powder for, 300 g</td>
<td>24</td>
<td>5</td>
<td>..</td>
<td>*1037.80</td>
<td>36.90</td>
</tr>
</tbody>
</table>

### ISOLEUCINE WITH CARBOHYDRATE

### Restricted benefit

**Maple syrup urine disease**

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
<th>Premium $ for Max. Qty</th>
<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>9436P</td>
<td>isoleucine with carbohydrate containing 1 g isoleucine oral liquid: powder for, 30 x 4 g sachets</td>
<td>4</td>
<td>5</td>
<td>..</td>
<td>*567.32</td>
<td>36.90</td>
</tr>
<tr>
<td>9134R</td>
<td>isoleucine with carbohydrate containing 50 mg isoleucine oral liquid: powder for, 30 x 4 g sachets</td>
<td>4</td>
<td>5</td>
<td>..</td>
<td>*516.36</td>
<td>36.90</td>
</tr>
</tbody>
</table>

### MILK PROTEIN AND FAT FORMULA WITH VITAMINS AND MINERALS CARBOHYDRATE FREE

### Restricted benefit

Patients with intractable seizures requiring treatment with a ketogenic diet

### Restricted benefit

Glucose transport protein defects

### Restricted benefit

Pyruvate dehydrogenase deficiency

### Restricted benefit

Infants and young children with glucose-galactose intolerance and multiple monosaccharide intolerance

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
<th>Premium $ for Max. Qty</th>
<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
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<tr>
<td>8630F</td>
<td>milk protein and fat formula with vitamins and minerals carbohydrate free oral liquid: powder for, 225 g</td>
<td>24</td>
<td>5</td>
<td>..</td>
<td>*648.76</td>
<td>36.90</td>
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### PHENYLALANINE WITH CARBOHYDRATE

### Restricted benefit

**Tyrosinaemia**

<table>
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<tr>
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<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
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<tr>
<td>9384X</td>
<td>phenylalanine with carbohydrate containing 50 mg phenylalanine oral liquid: powder for, 30 x 4 g sachets</td>
<td>4</td>
<td>5</td>
<td>..</td>
<td>*516.36</td>
<td>36.90</td>
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<tr>
<td>Code</td>
<td>Name, Restriction, Manner of Administration and Form</td>
<td>Max. Qty (Packs)</td>
<td>No. of Rpts</td>
<td>Dispensed Price for Max. Qty $</td>
<td>Premium $</td>
<td>Maximum Recordable Value for Safety Net $</td>
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<tr>
<td>8577K</td>
<td>SOY PROTEIN AND FAT FORMULA WITH VITAMINS AND MINERALS CARBOHYDRATE FREE</td>
<td>120</td>
<td>5</td>
<td>*670.36</td>
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<td></td>
<td>Patients with intractable seizures requiring treatment with a ketogenic diet</td>
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<tr>
<td></td>
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<td></td>
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</tr>
<tr>
<td></td>
<td>Glucose transport protein defects</td>
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</tr>
<tr>
<td></td>
<td>Restricted benefit</td>
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<td></td>
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<td></td>
</tr>
<tr>
<td></td>
<td>Pyruvate dehydrogenase deficiency</td>
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<td></td>
</tr>
<tr>
<td></td>
<td>Restricted benefit</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>Infants and young children with glucose-galactose intolerance and multiple monosaccharide intolerance</td>
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<tr>
<td>9308X</td>
<td>TRIGLYCERIDES LONG CHAIN WITH GLUCOSE POLYMER</td>
<td>6</td>
<td>5</td>
<td>*340.12</td>
<td>36.90</td>
<td>ProZero</td>
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<tr>
<td>9309Y</td>
<td>TRIGLYCERIDES MEDIUM CHAIN AND LONG CHAIN WITH GLUCOSE POLYMER</td>
<td>4</td>
<td>5</td>
<td>*304.36</td>
<td>36.90</td>
<td>ProZero</td>
</tr>
<tr>
<td>3136C</td>
<td>TRIGLYCERIDES MEDIUM CHAIN FORMULA</td>
<td>8</td>
<td>5</td>
<td>*295.88</td>
<td>36.90</td>
<td>Duocal</td>
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<tr>
<td>9383W</td>
<td>TYROSINE WITH CARBOHYDRATE</td>
<td>4</td>
<td>5</td>
<td>*253.96</td>
<td>36.90</td>
<td>MCT Pro-Cal</td>
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<tr>
<td>9165J</td>
<td>VALINE WITH CARBOHYDRATE</td>
<td>4</td>
<td>5</td>
<td>*516.36</td>
<td>36.90</td>
<td>Tyrosine 1000</td>
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<tr>
<td>9434M</td>
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<td>4</td>
<td>5</td>
<td>*567.32</td>
<td>36.90</td>
<td>Valine 1000</td>
</tr>
<tr>
<td>9135T</td>
<td>VALINE WITH CARBOHYDRATE</td>
<td>4</td>
<td>5</td>
<td>*516.36</td>
<td>36.90</td>
<td>Valine 50</td>
</tr>
</tbody>
</table>
## VITAMINS, MINERALS AND TRACE ELEMENTS WITH CARBOHYDRATE

**Authority required**
Infants and children whose vitamin and mineral intake is insufficient due to a specific diagnosis requiring a highly restrictive therapeutic diet, and whose vitamin, mineral and trace element needs cannot be adequately met with other proprietary vitamin and mineral preparations.

**Note**
Paediatric Seravit should only be used under strict supervision of a dietitian and a paediatrician.

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>Dispensed Price for Max. Qty $</th>
<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>NP</td>
<td>mg valine oral liquid: powder for, 30 x 4 g sachets</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>

**WHEY PROTEIN FORMULA SUPPLEMENTED WITH AMINO ACIDS, LONG CHAIN POLYUNSATURATED FATTY ACIDS, VITAMINS AND MINERALS, LOW IN PROTEIN, PHOSPHATE, POTASSIUM AND LACTOSE**

**Authority required**
Chronic renal failure

**Clinical criteria:**
Patient must require treatment with a low protein and a low phosphorus diet; OR
Patient must require treatment with a low protein, low phosphorus and low potassium diet.

**Population criteria:**
Patient must be an infant or a young child.

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>Dispensed Price for Max. Qty $</th>
<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>9328Y</td>
<td>vitamins, minerals and trace elements</td>
<td>6 5</td>
<td></td>
<td></td>
<td>*390.76</td>
<td>36.90</td>
<td>Paediatric Seravit SB</td>
</tr>
<tr>
<td>NP</td>
<td>whey protein formula supplemented with amino acids, long chain polyunsaturated fatty acids, vitamins and minerals, low in protein, phosphorus, potassium and lactose oral liquid: powder for, 10 x 100 g sachets</td>
<td>9 5</td>
<td></td>
<td></td>
<td>*1485.91</td>
<td>36.90</td>
<td>RenaStart VF</td>
</tr>
<tr>
<td>2870C</td>
<td>whey protein formula supplemented with amino acids, long chain polyunsaturated fatty acids, vitamins and minerals, low in protein, phosphorus, potassium and lactose oral liquid: powder for, 6 x 400 g cans</td>
<td>4 5</td>
<td></td>
<td></td>
<td>*1584.60</td>
<td>36.90</td>
<td>Renastart VF</td>
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</table>

**WHEY PROTEIN FORMULA SUPPLEMENTED WITH AMINO ACIDS, VITAMINS AND MINERALS, AND LOW IN PROTEIN, PHOSPHATE, POTASSIUM AND LACTOSE**

**Authority required**
Infants and young children with chronic renal failure requiring treatment with a low protein and a low phosphorus diet, or a low protein, a low phosphorus and a low potassium diet.

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
<th>Premium $</th>
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<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>8587Y</td>
<td>whey protein formula supplemented with amino acids, vitamins and minerals, and low in protein, phosphorus, potassium and lactose oral liquid: powder for, 400 g</td>
<td>16 5</td>
<td></td>
<td></td>
<td>*1066.28</td>
<td>36.90</td>
<td>Kindergen SB</td>
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</tbody>
</table>
Pharmaceutical Benefits for Palliative Care
<table>
<thead>
<tr>
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<th>No. of Rpts</th>
<th>Premium $</th>
<th>Dispensed Price for Max. Qty $</th>
<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>5385K NP</td>
<td>benzydamine hydrochloride 0.15% mouthwash, 500 mL</td>
<td>‡1 3 ..</td>
<td>22.60</td>
<td>23.75</td>
<td>Difflam IA</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5386L NP</td>
<td>benzydamine hydrochloride 0.15% mouthwash, 500 mL</td>
<td>‡1 ..</td>
<td>22.60</td>
<td>23.75</td>
<td>Difflam IA</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5334R NP</td>
<td>carmellose sodium 10 mg/mL oral spray, 100 mL</td>
<td>‡1 3 ..</td>
<td>13.49</td>
<td>14.64</td>
<td>Aquae VT</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5333Q NP</td>
<td>carmellose sodium 10 mg/mL oral spray, 25 mL</td>
<td>‡1 3 ..</td>
<td>11.64</td>
<td>12.79</td>
<td>Aquae VT</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5336W NP</td>
<td>carmellose sodium 10 mg/mL oral spray, 100 mL</td>
<td>‡1 ..</td>
<td>13.49</td>
<td>14.64</td>
<td>Aquae VT</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5335T NP</td>
<td>carmellose sodium 10 mg/mL oral spray, 25 mL</td>
<td>‡1 ..</td>
<td>11.64</td>
<td>12.79</td>
<td>Aquae VT</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5421H NP</td>
<td>HYPROMELLOSE Oral gel 20 mg per g. 100 g. 1</td>
<td>‡1 3 ..</td>
<td>12.73</td>
<td>13.88</td>
<td>Aquae Gel VT</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5422J NP</td>
<td>HYPROMELLOSE Oral gel 20 mg per g. 100 g. 1</td>
<td>‡1 ..</td>
<td>12.73</td>
<td>13.88</td>
<td>Aquae Gel VT</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS

#### BELLADONNA AND DERIVATIVES, PLAIN

*Belladonna alkaloids, semisynthetic, quaternary ammonium compounds*

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
<th>Premium $ (Max. Qty)</th>
<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>5317W</td>
<td><strong>HYOSCINE BUTYLBROMIDE</strong> Authority required (STREAMLINED) 3638 Initial supply, for up to 4 months, for a palliative care patient where colicky pain is a symptom</td>
<td>6</td>
<td>3</td>
<td><em>108.88</em></td>
<td>36.90</td>
<td>Buscopan BY</td>
</tr>
<tr>
<td>5318X</td>
<td><strong>HYOSCINE BUTYLBROMIDE</strong> Authority required (STREAMLINED) 3639 Continuing supply for a palliative care patient where colicky pain is a symptom Note Written or telephone authority applications for increased repeats may be approved where consultation with a palliative care specialist or service has occurred.</td>
<td>6</td>
<td>3</td>
<td><em>108.88</em></td>
<td>36.90</td>
<td>Buscopan BY</td>
</tr>
</tbody>
</table>

#### DRUGS FOR CONSTIPATION

##### Contact laxatives

**BISACODYL**

Authority required (STREAMLINED) 3642 Initial supply, for up to 4 months, for a palliative care patient where constipation is a problem | 5303D | bisacodyl 10 mg suppository, 10 | 3 | 3 | *21.28* | 22.43 | a Petrus Bisacodyl Suppositories PP
| 5304E | bisacodyl 10 mg suppository, 12 | 3 | 3 | *18.67* | 19.82 | a Petrus Bisacodyl Suppositories PP
| 5301B | bisacodyl 5 mg tablet: enteric, 200 tablets | 1 | 3 | 14.45 | 15.60 | Lax-Tab AS |

**BISACODYL**

Authority required (STREAMLINED) 3643 Continuing supply for a palliative care patient where constipation is a problem Note Written or telephone authority applications for increased repeats may be approved where consultation with a palliative care specialist or service has occurred. | 5307H | bisacodyl 10 mg suppository, 10 | 3 | ... | *21.28* | 22.43 | a Petrus Bisacodyl Suppositories PP
| 5308J | bisacodyl 10 mg suppository, 12 | 3 | ... | *18.67* | 19.82 | a Petrus Bisacodyl Suppositories PP
| 5305F | bisacodyl 5 mg tablet: enteric, 200 tablets | 1 | ... | 14.45 | 15.60 | Lax-Tab AS |

##### Bulk-forming laxatives

**RHAMNUS FRANGULA + STERCULIA**

Authority required (STREAMLINED) 3642 Initial supply, for up to 4 months, for a palliative care patient where constipation is a problem | 5322D | rhamnus frangula 80 mg/g + sterculia 620 mg/g granules, 500 g | ‡1 | 3 | 26.71 | 27.86 | Normacol Plus NE
## PREPARATIONS WHICH MAY BE PRESCRIBED FOR PATIENTS RECEIVING PALLIATIVE CARE

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
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<th>No. of Rpts</th>
<th>Premium $</th>
<th>Dispensed Price for Max. Qty $</th>
<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
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<tr>
<td></td>
<td>Continuing supply for a palliative care patient where constipation is a problem</td>
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<tr>
<td>Note</td>
<td>Written or telephone authority applications for increased repeats may be approved where consultation with a palliative care specialist or service has occurred.</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>5324F</td>
<td>rhhamnus frangula 80 mg/g + sterculia 620 mg/g granules, 500 g</td>
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<tr>
<td></td>
<td><strong>Osmotically acting laxatives</strong></td>
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<tr>
<td>3642</td>
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<td></td>
<td>Initial supply, for up to 4 months, for a palliative care patient where constipation is a problem</td>
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<tr>
<td>5387M</td>
<td>LACTULOSE Mixture 3.34 g per 5 mL, 500 mL, 1</td>
<td>3</td>
<td>3</td>
<td>...</td>
<td><strong>18.58</strong></td>
<td>19.73 a Genlac QA</td>
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<tr>
<td>NP</td>
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<tr>
<td>5388N</td>
<td>LACTULOSE Mixture 3.34 g per 5 mL, 500 mL, 1</td>
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<td>...</td>
<td>...</td>
<td><strong>18.58</strong></td>
<td>19.73 a Genlac QA</td>
<td></td>
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<td>4176</td>
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<td>Constipation Treatment Phase: Initial treatment</td>
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<td>Clinical criteria:</td>
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<tr>
<td></td>
<td>Patient must be receiving palliative care.</td>
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<td></td>
<td>AND</td>
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<tr>
<td></td>
<td>Patient must not receive more than 4 months treatment under this restriction.</td>
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<tr>
<td>Note</td>
<td>Pharmaceutical benefits that have the form macrogol-3350 1 g/g oral liquid: powder for, 510 g and pharmaceutical benefits that have the form macrogol-3350 1 g/g oral liquid: powder for, 30 x 17 g sachets are equivalent for the purposes of substitution.</td>
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<tr>
<td>2351R</td>
<td>macrogol-3350 1 g/g oral liquid: powder for, 30 x 17 g sachets</td>
<td>2</td>
<td>3</td>
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<td><strong>35.02</strong></td>
<td>36.17 a MediHealth ClearLax ON</td>
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<tr>
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<tr>
<td>5426N</td>
<td>macrogol-3350 1 g/g oral liquid: powder for, 510 g</td>
<td>2</td>
<td>3</td>
<td>...</td>
<td><strong>35.02</strong></td>
<td>36.17 a OsmoLax KY</td>
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<td></td>
<td>**MACROGOL-3350 Authority required (STREAMLINED)</td>
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</tr>
<tr>
<td>4170</td>
<td>Constipation Treatment Phase: Continuing treatment</td>
<td></td>
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</tr>
<tr>
<td></td>
<td>Clinical criteria:</td>
<td></td>
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</tr>
<tr>
<td></td>
<td>Patient must be receiving palliative care.</td>
<td></td>
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<tr>
<td>Note</td>
<td>Written or telephone authority applications for increased repeats may be approved where consultation with a palliative care specialist or service has occurred.</td>
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<td>Dispensed Price for Max. Qty</td>
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<tr>
<td>2353W</td>
<td>macrogol-3350 1 g/g oral liquid: powder for, 30 x 17 g sachets</td>
<td>2</td>
<td>..</td>
<td>..</td>
<td>*35.02</td>
<td>36.17</td>
<td>a</td>
</tr>
<tr>
<td>5427P</td>
<td>macrogol-3350 1 g/g oral liquid: powder for, 510 g</td>
<td>2</td>
<td>..</td>
<td>..</td>
<td>*35.02</td>
<td>36.17</td>
<td>a</td>
</tr>
</tbody>
</table>

### MACROGOL-3350 + SODIUM CHLORIDE + POTASSIUM CHLORIDE + BICARBONATE

**Authority required (STREAMLINED)**

4595

Constipation

**Treatment Phase:** Initial treatment

**Clinical criteria:**

Patient must be receiving palliative care.

**AND**

Patient must not receive more than 4 months treatment under this restriction.

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
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<th>Premium $</th>
<th>Dispensed Price for Max. Qty</th>
<th>Maximum Recordable Value for Safety Net</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>5389P</td>
<td>macrogol-3350 13.12 g + sodium chloride 350.7 mg + potassium chloride 46.6 mg (0.63 mmol potassium) + sodium bicarbonate 178.5 mg solution, 30 sachets</td>
<td>2</td>
<td>3</td>
<td>..</td>
<td>*35.02</td>
<td>36.17</td>
<td>a</td>
<td></td>
<td>APO-MACROGOL plus ELECTROLYTES</td>
</tr>
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<td>LaxaCon</td>
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<td>lax-sachets</td>
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<td></td>
<td>Molaxole</td>
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<td></td>
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<td></td>
<td></td>
<td>Movicol</td>
</tr>
<tr>
<td>10127B</td>
<td>macrogol-3350 13.12 g/25 mL + sodium chloride 350.7 mg/25 mL + potassium chloride 46.6 mg/25 mL (0.63 mmol/25 mL potassium) + sodium bicarbonate 178.5 mg/25 mL oral liquid, 500 mL</td>
<td>2</td>
<td>3</td>
<td>..</td>
<td>*25.60</td>
<td>26.75</td>
<td>a</td>
<td></td>
<td>Movicol Liquid</td>
</tr>
</tbody>
</table>

### MACROGOL-3350 + SODIUM CHLORIDE + POTASSIUM CHLORIDE + BICARBONATE

**Authority required (STREAMLINED)**

4590

Constipation

**Treatment Phase:** Continuing treatment

**Clinical criteria:**

Patient must be receiving palliative care.

**Note**

Written or telephone authority applications for increased repeats may be approved where consultation with a palliative care specialist or service has occurred.

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
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<th>Maximum Recordable Value for Safety Net</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>5390Q</td>
<td>macrogol-3350 13.12 g + sodium chloride 350.7 mg + potassium chloride 46.6 mg (0.63 mmol potassium) + sodium bicarbonate 178.5 mg solution, 30 sachets</td>
<td>2</td>
<td>..</td>
<td>..</td>
<td>*35.02</td>
<td>36.17</td>
<td>a</td>
<td></td>
<td>APO-MACROGOL plus ELECTROLYTES</td>
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<td>LaxaCon</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>lax-sachets</td>
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<td>Molaxole</td>
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<td></td>
<td></td>
<td></td>
<td>Movicol</td>
</tr>
<tr>
<td>10112F</td>
<td>macrogol-3350 13.12 g/25 mL + sodium chloride 350.7 mg/25 mL + potassium chloride 46.6 mg/25 mL (0.63 mmol/25 mL potassium) + sodium bicarbonate 178.5 mg/25 mL oral liquid, 500 mL</td>
<td>2</td>
<td>..</td>
<td>..</td>
<td>*25.60</td>
<td>26.75</td>
<td>a</td>
<td></td>
<td>Movicol Liquid</td>
</tr>
</tbody>
</table>

## Enemas

**BISACODYL**

**Authority required (STREAMLINED)**
### PREPARATIONS WHICH MAY BE PRESCRIBED FOR PATIENTS RECEIVING PALLIATIVE CARE

<table>
<thead>
<tr>
<th>Code</th>
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<th>No. of Rpts</th>
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<th>Dispensed Price for Max. Qty $</th>
<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>3642</td>
<td>Initial supply, for up to 4 months, for a palliative care patient where constipation is a problem</td>
<td>1</td>
<td>3</td>
<td>38.28</td>
<td>36.90</td>
<td>36.90</td>
<td>Bisalax AS</td>
</tr>
</tbody>
</table>

**BISACODYL**

**Authority required (STREAMLINED)**

3643
Continuing supply for a palliative care patient where constipation is a problem

**Note**
Written or telephone authority applications for increased repeats may be approved where consultation with a palliative care specialist or service has occurred.

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
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<th>No. of Rpts</th>
<th>Premium $</th>
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<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>5306G</td>
<td>bisacodyl 10 mg/5 mL enema, 25 x 5 mL</td>
<td>1</td>
<td>..</td>
<td>38.28</td>
<td>36.90</td>
<td>36.90</td>
<td>Bisalax AS</td>
</tr>
</tbody>
</table>

**SORBITOL + CITRATE + LAURYL SULFOACETATE SODIUM**

**Authority required (STREAMLINED)**

3642
Initial supply, for up to 4 months, for a palliative care patient where constipation is a problem

**Note**
Written or telephone authority applications for increased repeats may be approved where consultation with a palliative care specialist or service has occurred.

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
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<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>5331N</td>
<td>sorbitol 3.125 g/5 mL + citrate sodium dihydrate 450 mg/5 mL + lauryl sulfoacetate sodium 45 mg/5 mL enema, 12 x 5 mL</td>
<td>2</td>
<td>3</td>
<td>32.62</td>
<td>33.77</td>
<td>a Micolette AE</td>
<td>Microlax JT</td>
</tr>
</tbody>
</table>

**SORBITOL + CITRATE + LAURYL SULFOACETATE SODIUM**

**Authority required (STREAMLINED)**

3643
Continuing supply for a palliative care patient where constipation is a problem

**Note**
Written or telephone authority applications for increased repeats may be approved where consultation with a palliative care specialist or service has occurred.

<table>
<thead>
<tr>
<th>Code</th>
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<th>Dispensed Price for Max. Qty $</th>
<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>5332P</td>
<td>sorbitol 3.125 g/5 mL + citrate sodium dihydrate 450 mg/5 mL + lauryl sulfoacetate sodium 45 mg/5 mL enema, 12 x 5 mL</td>
<td>2</td>
<td>..</td>
<td>32.62</td>
<td>33.77</td>
<td>a Micolette AE</td>
<td>Microlax JT</td>
</tr>
</tbody>
</table>

**Peripheral opioid receptor antagonists**

**METHYLNALTREXONE**

**Authority required**
Continuing supply, in combination with oral laxatives, for a palliative care patient with opioid-induced constipation who has demonstrated a response to methylnaltrexone

**Note**
For first continuing supply, applications for increased repeats may be authorised.
Where consultation with a palliative care specialist or service has occurred, applications for increased repeats may be authorised.

**Note**
Special Pricing Arrangements apply.

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
<th>Premium $</th>
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<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>5424L</td>
<td>METHYLNALTREXONE Solution for injection containing methylnaltrexone bromide 12 mg in 0.6 mL, 7</td>
<td>1</td>
<td>..</td>
<td>288.18</td>
<td>36.90</td>
<td>36.90</td>
<td>Relistor LM</td>
</tr>
</tbody>
</table>

**METHYLNALTREXONE**

**Authority required**
Initial supply, in combination with oral laxatives, for a palliative care patient with opioid-induced constipation who has failed to respond to laxatives

**Note**
No applications for repeats will be authorised.

**Note**
Special Pricing Arrangements apply.

<table>
<thead>
<tr>
<th>Code</th>
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<th>No. of Rpts</th>
<th>Premium $</th>
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<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>5423K</td>
<td>methylnaltrexone bromide 12 mg/0.6 mL injection, 1 x 0.6 mL vial</td>
<td>3</td>
<td>..</td>
<td>130.93</td>
<td>36.90</td>
<td>36.90</td>
<td>Relistor LM</td>
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**Other drugs for constipation**
### PREPARATIONS WHICH MAY BE PRESCRIBED FOR PATIENTS RECEIVING PALLIATIVE CARE

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<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
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<th>Dispensed Price for Max. Qty $</th>
<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>5312N</td>
<td>glycerol 1.4 g suppository, 12 3 3 .. *20.23 21.38</td>
<td>Petrus Pharmaceuticals Pty Ltd PP</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>5313P</td>
<td>glycerol 2.8 g suppository, 12 3 3 .. *20.74 21.89</td>
<td>Petrus Pharmaceuticals Pty Ltd PP</td>
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<tr>
<td>5311M</td>
<td>glycerol 700 mg suppository, 12 3 3 .. *19.81 20.96</td>
<td>Petrus Pharmaceuticals Pty Ltd PP</td>
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</tbody>
</table>

**GLYCEROL**

**Authority required (STREAMLINED)**

**3642**

Initial supply, for up to 4 months, for a palliative care patient where constipation is a problem

**Note**

Written or telephone authority applications for increased repeats may be approved where consultation with a palliative care specialist or service has occurred.

<table>
<thead>
<tr>
<th>Code</th>
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<th>Max. Qty (Packs)</th>
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<th>Premium $/Max. Qty</th>
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<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
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<td>glycerol 1.4 g suppository, 12 3 .. .. *20.23 21.38</td>
<td>Petrus Pharmaceuticals Pty Ltd PP</td>
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<td></td>
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</tr>
<tr>
<td>5316T</td>
<td>glycerol 2.8 g suppository, 12 3 .. .. *20.74 21.89</td>
<td>Petrus Pharmaceuticals Pty Ltd PP</td>
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<tr>
<td>5314Q</td>
<td>glycerol 700 mg suppository, 12 3 .. .. *19.81 20.96</td>
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</table>
### PREPARATIONS WHICH MAY BE PRESCRIBED FOR PATIENTS RECEIVING PALLIATIVE CARE

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<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>5363G NP</td>
<td>diclofenac sodium 100 mg suppository, 20</td>
<td>2 3</td>
<td>..</td>
<td>*25.26</td>
<td>26.41</td>
<td>Voltaren 100</td>
<td>NV</td>
</tr>
<tr>
<td>5366K NP</td>
<td>diclofenac sodium 100 mg suppository, 20</td>
<td>2</td>
<td>..</td>
<td>..</td>
<td>..</td>
<td>..</td>
<td>..</td>
</tr>
<tr>
<td>5361E NP</td>
<td>diclofenac sodium 25 mg tablet: enteric, 50 tablets</td>
<td>2 3</td>
<td>..</td>
<td>*11.10</td>
<td>12.25</td>
<td>APO-Diclofenac</td>
<td>TX</td>
</tr>
<tr>
<td>5362F NP</td>
<td>diclofenac sodium 50 mg tablet: enteric, 50 tablets</td>
<td>1 3</td>
<td>..</td>
<td>81.62</td>
<td>12.72</td>
<td>12.25</td>
<td>APO-Diclofenac</td>
</tr>
<tr>
<td>5364H NP</td>
<td>diclofenac sodium 25 mg tablet: enteric, 50 tablets</td>
<td>2</td>
<td>..</td>
<td>..</td>
<td>*11.10</td>
<td>12.25</td>
<td>APO-Diclofenac</td>
</tr>
</tbody>
</table>

### MUSCULO-SKELETAL SYSTEM

### ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS

**Acetic acid derivatives and related substances**

#### DICLOFENAC

**Authority required**

Initial supply, for up to 4 months, for a palliative care patient where severe pain is a problem

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
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<td>..</td>
<td>*25.26</td>
<td>26.41</td>
<td>Voltaren 100</td>
<td>NV</td>
</tr>
</tbody>
</table>

**Authority required**

Continuing supply for a palliative care patient where severe pain is a problem

**Note**

Written or telephone authority applications for increased repeats may be approved where consultation with a palliative care specialist or service has occurred.

<table>
<thead>
<tr>
<th>Code</th>
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</tr>
</thead>
<tbody>
<tr>
<td>5366K NP</td>
<td>diclofenac sodium 100 mg suppository, 20</td>
<td>2</td>
<td>..</td>
<td>..</td>
<td>..</td>
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<td>..</td>
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</tbody>
</table>

#### DICLOFENAC

**Authority required (STREAMLINED)**

3645

Initial supply, for up to 4 months, for a palliative care patient where severe pain is a problem

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>Dispensed Price for Max. Qty $</th>
<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>5361E NP</td>
<td>diclofenac sodium 25 mg tablet: enteric, 50 tablets</td>
<td>2 3</td>
<td>..</td>
<td>*11.10</td>
<td>12.25</td>
<td>APO-Diclofenac</td>
<td>TX</td>
</tr>
<tr>
<td>5362F NP</td>
<td>diclofenac sodium 50 mg tablet: enteric, 50 tablets</td>
<td>1 3</td>
<td>..</td>
<td>81.62</td>
<td>12.72</td>
<td>12.25</td>
<td>APO-Diclofenac</td>
</tr>
</tbody>
</table>

#### DICLOFENAC

**Authority required (STREAMLINED)**

3644

Continuing supply for a palliative care patient where severe pain is a problem

**Note**

Written or telephone authority applications for increased repeats may be approved where consultation with a palliative care specialist or service has occurred.

<table>
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<tr>
<th>Code</th>
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<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>5364H NP</td>
<td>diclofenac sodium 25 mg tablet: enteric, 50 tablets</td>
<td>2</td>
<td>..</td>
<td>..</td>
<td>*11.10</td>
<td>12.25</td>
<td>APO-Diclofenac</td>
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</tbody>
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Note: The above information is a simplified representation of the original text. The full details and specific conditions for each preparation are provided in the original document.
### PREPARATIONS WHICH MAY BE PRESCRIBED FOR PATIENTS RECEIVING PALLIATIVE CARE

<table>
<thead>
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<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>5365J</td>
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<td>9.78</td>
<td>12.25</td>
<td>10.93</td>
<td>a Terry White Chemists Diclofenac TW, a Voltaren 25 NV</td>
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<tr>
<td></td>
<td></td>
<td>81.62</td>
<td></td>
<td>*12.72</td>
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<tr>
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<td></td>
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<td></td>
<td></td>
<td>a Cylon 50 QA</td>
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<td></td>
<td></td>
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<td></td>
<td>11.39</td>
<td>10.93</td>
<td>a Voltaren 50 NV</td>
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</table>

**INDOMETHACIN**

**Authority required**

Initial supply, for up to 4 months, for a palliative care patient where severe pain is a problem

<table>
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<tr>
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<th>Name, Restriction, Manner of Administration and Form</th>
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<th>Premium $</th>
<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>5378C</td>
<td>indomethacin 100 mg suppository, 20</td>
<td>2</td>
<td>3</td>
<td>*22.84</td>
<td>23.99</td>
<td></td>
<td>Indocid AS</td>
</tr>
</tbody>
</table>

**INDOMETHACIN**

**Authority required**

Continuing supply for a palliative care patient where severe pain is a problem

**Note**

Written or telephone authority applications for increased repeats may be approved where consultation with a palliative care specialist or service has occurred.

<table>
<thead>
<tr>
<th>Code</th>
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</tr>
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<tbody>
<tr>
<td>5380E</td>
<td>indomethacin 100 mg suppository, 20</td>
<td>2</td>
<td>..</td>
<td>*22.84</td>
<td>23.99</td>
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<td>Indocid AS</td>
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**INDOMETHACIN**

**Authority required (STREAMLINED)**

3645

Initial supply, for up to 4 months, for a palliative care patient where severe pain is a problem

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<tr>
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<td>3</td>
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<td>13.91</td>
<td>a Arthrexin AF</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>4.64</td>
<td></td>
<td>*17.40</td>
<td>13.91</td>
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<td>Indocid AS</td>
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</table>

**INDOMETHACIN**

**Authority required (STREAMLINED)**

3646

Continuing supply for a palliative care patient where severe pain is a problem

**Note**

Written or telephone authority applications for increased repeats may be approved where consultation with a palliative care specialist or service has occurred.

<table>
<thead>
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<td>*12.76</td>
<td>13.91</td>
<td>a Arthrexin AF</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>4.64</td>
<td></td>
<td>*17.40</td>
<td>13.91</td>
<td></td>
<td>Indocid AS</td>
</tr>
</tbody>
</table>

**Propionic acid derivatives**

**IBUPROFEN**

**Authority required**

Initial supply, for up to 4 months, for a palliative care patient where severe pain is a problem

<table>
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<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
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<tbody>
<tr>
<td>5368M</td>
<td>ibuprofen 400 mg tablet, 30</td>
<td>3</td>
<td>3</td>
<td>*15.07</td>
<td>16.22</td>
<td></td>
<td>Brufen AB</td>
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</table>

**IBUPROFEN**

**Authority required**

Continuing supply for a palliative care patient where severe pain is a problem

**Note**

Written or telephone authority applications for increased repeats may be approved where consultation with a palliative care specialist or service has occurred.

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<tr>
<td>5370P</td>
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<td>..</td>
<td>*15.07</td>
<td>16.22</td>
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<td>Brufen AB</td>
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</table>
### PREPARATIONS WHICH MAY BE PRESCRIBED FOR PATIENTS RECEIVING PALLIATIVE CARE

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<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
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<tr>
<td>5348L</td>
<td>naproxen 1 g tablet: modified release, 28</td>
<td>1</td>
<td>3</td>
<td>$1.29</td>
<td>15.59</td>
<td>15.45</td>
<td>Proxen SR 1000 MD</td>
</tr>
<tr>
<td>5345H</td>
<td>naproxen 250 mg tablet, 50</td>
<td>2</td>
<td>3</td>
<td>$2.24</td>
<td>*15.92</td>
<td>14.83</td>
<td>Naprosyn SR1000 RO</td>
</tr>
<tr>
<td>5346J</td>
<td>naproxen 500 mg tablet, 50</td>
<td>1</td>
<td>3</td>
<td>$1.28</td>
<td>14.22</td>
<td>14.09</td>
<td>Naprosyn RO AF</td>
</tr>
<tr>
<td>5347K</td>
<td>naproxen 750 mg tablet: modified release, 28 tablets</td>
<td>1</td>
<td>3</td>
<td>$1.22</td>
<td>13.64</td>
<td>13.57</td>
<td>Proxen SR 750 MD</td>
</tr>
</tbody>
</table>

**NAPROXEN Authority required (STREAMLINED) 3645**

Initial supply, for up to 4 months, for a palliative care patient where severe pain is a problem

**Note**

Written or telephone authority applications for increased repeats may be approved where consultation with a palliative care specialist or service has occurred.

<table>
<thead>
<tr>
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<td>$1.29</td>
<td>15.59</td>
<td>15.45</td>
<td>Proxen SR 1000 MD</td>
</tr>
<tr>
<td>5349M</td>
<td>naproxen 250 mg tablet, 50</td>
<td>2</td>
<td>...</td>
<td>$2.24</td>
<td>*15.92</td>
<td>14.83</td>
<td>Naprosyn SR1000 RO</td>
</tr>
<tr>
<td>5350N</td>
<td>naproxen 500 mg tablet, 50</td>
<td>1</td>
<td>...</td>
<td>$1.28</td>
<td>14.22</td>
<td>14.09</td>
<td>Naprosyn RO AF</td>
</tr>
<tr>
<td>5351P</td>
<td>naproxen 750 mg tablet: modified release, 28 tablets</td>
<td>1</td>
<td>...</td>
<td>$1.22</td>
<td>13.64</td>
<td>13.57</td>
<td>Proxen SR 750 MD</td>
</tr>
</tbody>
</table>

**NAPROXEN Authority required (STREAMLINED) 3646**

Continuing supply for a palliative care patient where severe pain is a problem

**Note**

Written or telephone authority applications for increased repeats may be approved where consultation with a palliative care specialist or service has occurred.

<table>
<thead>
<tr>
<th>Code</th>
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<tbody>
<tr>
<td>5352Q</td>
<td>naproxen 1 g tablet: modified release, 28</td>
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<td>...</td>
<td>$1.29</td>
<td>15.59</td>
<td>15.45</td>
<td>Proxen SR 1000 MD</td>
</tr>
<tr>
<td>5349M</td>
<td>naproxen 250 mg tablet, 50</td>
<td>2</td>
<td>...</td>
<td>$2.24</td>
<td>*15.92</td>
<td>14.83</td>
<td>Naprosyn SR1000 RO</td>
</tr>
<tr>
<td>5350N</td>
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<td>$1.28</td>
<td>14.22</td>
<td>14.09</td>
<td>Naprosyn RO AF</td>
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<tr>
<td>5351P</td>
<td>naproxen 750 mg tablet: modified release, 28 tablets</td>
<td>1</td>
<td>...</td>
<td>$1.22</td>
<td>13.64</td>
<td>13.57</td>
<td>Proxen SR 750 MD</td>
</tr>
</tbody>
</table>

**NAPROXEN Authority required (STREAMLINED) 4128**

Severe pain

**Clinical criteria:**

Patient must be unable to take a solid dose form of a non-steroidal anti-inflammatory agent, AND Patient must not receive more than 4 months treatment under this restriction.

**Treatment criteria:**

Patient must be undergoing palliative care.

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
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<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>5397C</td>
<td>naproxen 125 mg/5 mL oral liquid, 474 mL</td>
<td>1</td>
<td>3</td>
<td>78.51</td>
<td>36.90</td>
<td>Phebra Naproxen Suspension PL</td>
<td></td>
</tr>
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**NAPROXEN Authority required (STREAMLINED) 4129**

Severe pain

**Clinical criteria:**

Patient must be unable to take a solid dose form of a non-steroidal anti-inflammatory agent.

**Treatment criteria:**

...
PREPARATIONS WHICH MAY BE PRESCRIBED FOR
PATIENTS RECEIVING PALLIATIVE CARE

<table>
<thead>
<tr>
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<tr>
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<td>78.51</td>
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<td>Phebra Naproxen Suspension</td>
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<tr>
<td></td>
<td>Administered initially, for up to 4 months, for a</td>
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<td></td>
<td></td>
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<tr>
<td></td>
<td>palliative care patient where severe pain is a</td>
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<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td></td>
<td>problem</td>
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<tr>
<td></td>
<td>consultation with a palliative care specialist or</td>
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<tr>
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<tr>
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<td>naproxen sodium 550 mg tablet, 50</td>
<td>1</td>
<td>3</td>
<td>13.11</td>
<td>14.26</td>
<td>a Crysanal MD</td>
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<td>3646</td>
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<tr>
<td></td>
<td>Administered in a continuing supply for a palliative</td>
<td></td>
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<td>care patient where severe pain is a problem</td>
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<td>Note:</td>
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<td></td>
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<td></td>
<td>Written or telephone authority applications for</td>
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<tr>
<td></td>
<td>consultation with a palliative care specialist or</td>
<td></td>
<td></td>
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<td></td>
<td>service has occurred.</td>
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<td>..</td>
<td>13.11</td>
<td>14.26</td>
<td>a Crysanal MD</td>
</tr>
<tr>
<td></td>
<td>Note:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Naproxen sodium 550 mg is approximately equivalent</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>to 500 mg of naproxen acid.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Patient must be undergoing palliative care.

Note: Written or telephone authority applications for increased repeats may be approved where consultation with a palliative care specialist or service has occurred.

Note: Naproxen sodium 550 mg is approximately equivalent to 500 mg of naproxen acid.
### NERVOUS SYSTEM

#### ANALGESICS

##### OPIOIDS

**Natural opium alkaloids**

**MORPHINE**

*Authority required*

Initial supply, for up to 3 months, for a palliative care patient with severe disabling pain not responding to non-narcotic analgesics

*Caution*

The risk of drug dependence is high.

*Note*

Telephone approvals are limited to 1 month’s therapy.

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>5393W NP</td>
<td>morphine sulfate 10 mg tablet, 20</td>
<td>1</td>
<td>2</td>
<td>..</td>
<td>14.66</td>
<td>15.81</td>
</tr>
<tr>
<td>5394X NP</td>
<td>morphine sulfate 20 mg tablet, 20</td>
<td>1</td>
<td>2</td>
<td>..</td>
<td>15.60</td>
<td>16.75</td>
</tr>
</tbody>
</table>

**MORPHINE**

*Authority required*

Continuing supply for a palliative care patient with severe disabling pain not responding to non-narcotic analgesics

*Caution*

The risk of drug dependence is high.

*Note*

Where consultation with a palliative care specialist or service has occurred, applications for increased repeats for up to 3 months’ supply may be authorised.

Telephone approvals are limited to 1 month’s therapy.

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty</th>
<th>No. of Rpts</th>
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<tr>
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<td>..</td>
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<td>15.81</td>
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<td>5396B NP</td>
<td>morphine sulfate 20 mg tablet, 20</td>
<td>1</td>
<td>..</td>
<td>..</td>
<td>15.60</td>
<td>16.75</td>
</tr>
</tbody>
</table>

**MORPHINE**

*Authority required*

Initial supply, for up to 3 months, for a palliative care patient with chronic severe disabling pain not responding to non-narcotic analgesics

*Caution*

The risk of drug dependence is high.

*Note*

Telephone approvals are limited to 1 month’s therapy.

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty</th>
<th>No. of Rpts</th>
<th>Premium $</th>
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<tr>
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<td>morphine sulfate 200 mg tablet: modified release, 28 tablets</td>
<td>1</td>
<td>2</td>
<td>..</td>
<td>122.20</td>
<td>36.90</td>
</tr>
</tbody>
</table>

**MORPHINE**

*Authority required*

Continuing supply for a palliative care patient with chronic severe disabling pain not responding to non-narcotic analgesics

*Caution*

The risk of drug dependence is high.

*Note*

Where consultation with a palliative care specialist or service has occurred, applications for increased repeats for up to 3 months’ supply may be authorised.

Telephone approvals are limited to 1 month’s therapy.

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty</th>
<th>No. of Rpts</th>
<th>Premium $</th>
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<tr>
<td>5392T NP</td>
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<td>..</td>
<td>..</td>
<td>122.20</td>
<td>36.90</td>
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**Phenylpiperidine derivatives**

**FENTANYL**

*Authority required*

Breakthrough pain
### PREPARATIONS WHICH MAY BE PRESCRIBED FOR PATIENTS RECEIVING PALLIATIVE CARE

<table>
<thead>
<tr>
<th>Code</th>
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<th>Brand Name and Manufacturer</th>
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<td>36.90</td>
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<td>Actiq OA</td>
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<td>36.90</td>
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<tr>
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<td>36.90</td>
<td>Actiq OA</td>
</tr>
</tbody>
</table>

**FENTANYL**

*Authority required*

Breakthrough pain

**Clinical criteria:**

Patient must have cancer,

AND

Patient must be receiving opioids for their persistent pain,

AND

Patient must be unable to tolerate further escalation in the dose of morphine for breakthrough pain due to adverse effects.

**Treatment criteria:**

Patient must be undergoing palliative care.

Caution

The risk of drug dependence is high.

**Note**

No increase in the maximum number of repeats may be authorised.

**Note**

Where consultation with a palliative care specialist or service has occurred, applications for increased repeats for up to 3 months’ supply may be authorised.

**Note**

Telephone approvals are limited to 1 months’ therapy.

**Note**

Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

---

**Treatment Phase: Continuing treatment**

**Clinical criteria:**

Patient must have cancer,

AND

Patient must be receiving opioids for their persistent pain,

AND

Patient must be unable to tolerate further escalation in the dose of morphine for breakthrough pain due to adverse effects.

**Treatment criteria:**

Patient must be undergoing palliative care.

Caution

The risk of drug dependence is high.

**Note**

For first continuing supply, applications for increased repeats for up to 3 months’ supply may be authorised.

**Note**

Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

---

**Treatment Phase: Initial treatment for dose titration**

**Clinical criteria:**

Patient must have cancer,

AND

Patient must be receiving opioids for their persistent pain,

AND

Patient must be unable to tolerate further escalation in the dose of morphine for breakthrough pain due to adverse effects.

**Treatment criteria:**

Patient must be undergoing palliative care.

Caution

The risk of drug dependence is high.

**Note**

No increase in the maximum number of repeats may be authorised.

**Note**

Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.
PREPARATIONS WHICH MAY BE PRESCRIBED FOR PATIENTS RECEIVING PALLIATIVE CARE

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<thead>
<tr>
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<th>Name, Restriction, Manner of Administration and Form</th>
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<td>..</td>
<td>99.95</td>
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<td>..</td>
<td>99.95</td>
<td>36.90</td>
<td></td>
<td>Actiq OA</td>
</tr>
</tbody>
</table>

**Diphenylpropylamine derivatives**

**METHADONE**

*Authority required*

Initial supply, for up to 3 months, for a palliative care patient with chronic severe disabling pain not responding to non-narcotic analgesics

**Caution**
The risk of drug dependence is high.

**Note**
Telephone approvals are limited to 1 month's therapy.

**Note**
Shared Care Model:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

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<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
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<td>1</td>
<td>2</td>
<td>19.25</td>
<td>20.40</td>
<td></td>
<td>Aspen Methadone Syrup QA</td>
</tr>
</tbody>
</table>

**METHADONE**

*Authority required*

Continuing supply for a palliative care patient with chronic severe disabling pain not responding to non-narcotic analgesics

**Caution**
The risk of drug dependence is high.

**Note**
Where consultation with a palliative care specialist or service has occurred, applications for increased repeats for up to 3 months' supply may be authorised.

**Note**
Telephone approvals are limited to 1 month's therapy.

**Note**
Shared Care Model:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

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<td>..</td>
<td>19.25</td>
<td>20.40</td>
<td></td>
<td>Aspen Methadone Syrup QA</td>
</tr>
</tbody>
</table>

**OTHER ANALGESICS AND ANTIPIRETICS**

**Anilides**

**PARACETAMOL**

*Authority required (STREAMLINED)*

Initial supply, for up to 4 months, for a palliative care patient for analgesia or fever where alternative therapy cannot be tolerated

<table>
<thead>
<tr>
<th>Code</th>
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<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>NP</td>
<td>paracetamol 500 mg suppository, 24</td>
<td>4</td>
<td>3</td>
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<td>36.90</td>
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<td>Panadol GC</td>
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<tr>
<td>NP</td>
<td>paracetamol 665 mg tablet: modified release, 96 tablets</td>
<td>2</td>
<td>3</td>
<td>*16.98</td>
<td>18.13</td>
<td></td>
<td>Panadol Osteo GC</td>
</tr>
</tbody>
</table>

**PARACETAMOL**

*Authority required (STREAMLINED)*

Continuing supply for a palliative care patient for analgesia or fever where alternative therapy cannot be tolerated

**Note**
Written or telephone authority applications for increased repeats may be approved where consultation with a palliative care specialist or service has occurred.
## PREPARATIONS WHICH MAY BE PRESCRIBED FOR PATIENTS RECEIVING PALLIATIVE CARE

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<tr>
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<td>..</td>
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<td>36.90</td>
<td>Panadol GC</td>
</tr>
<tr>
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<td>..</td>
<td>..</td>
<td>*16.98</td>
<td>18.13</td>
<td>Panadol Osteo GC</td>
</tr>
</tbody>
</table>

### ANTIEPILEPTICS

#### Benzodiazepine derivatives

**CLONAZEPAM**

**Authority required**

Initial supply, for up to 4 months, for a palliative care patient for the prevention of epilepsy

**Note**

No applications for increased repeats will be authorised.

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
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<tbody>
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<td>clonazepam 2 mg tablet, 100</td>
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<td>3</td>
<td>..</td>
<td>19.08</td>
<td>20.23</td>
<td>a Paxam 2 AF</td>
</tr>
<tr>
<td>5339B NP</td>
<td>clonazepam 2.5 mg/mL oral liquid, 10 mL</td>
<td>2</td>
<td>3</td>
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<td>16.53</td>
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<td>14.45</td>
<td>a Paxam 0.5 AF</td>
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<tr>
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<td>20.23</td>
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<td>5342E NP</td>
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<tr>
<td>5355W NP</td>
<td>Diazepam 2 mg tablet, 50</td>
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<td>3</td>
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<td>9.07</td>
<td>a Antenex 2 AF</td>
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<tr>
<td>5356X NP</td>
<td>Diazepam 5 mg tablet, 50</td>
<td>1</td>
<td>3</td>
<td>..</td>
<td>8.04</td>
<td>9.19</td>
<td>a Antenex 5 AF</td>
</tr>
</tbody>
</table>

### PSYCHOLEPTICS

#### ANXIOLYTICS

**Benzodiazepine derivatives**

**DIAZEPAM**

**Authority required**

Initial supply, for up to 4 months, for a palliative care patient where anxiety is a problem

**Note**

No applications for increased repeats will be authorised.

<table>
<thead>
<tr>
<th>Code</th>
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<tr>
<td>5338Y NP</td>
<td>Diazepam 2 mg tablet, 50</td>
<td>1</td>
<td>3</td>
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<td>7.92</td>
<td>9.07</td>
<td>a Antenex 2 AF</td>
</tr>
<tr>
<td>5339B NP</td>
<td>Diazepam 2.5 mg/mL oral liquid, 10 mL</td>
<td>2</td>
<td>..</td>
<td>..</td>
<td>*8.66</td>
<td>9.07</td>
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<td>5337X NP</td>
<td>Diazepam 500 microgram tablet, 100</td>
<td>1</td>
<td>..</td>
<td>..</td>
<td>8.04</td>
<td>9.19</td>
<td>a Antenex 5 AF</td>
</tr>
</tbody>
</table>

## Notes

- *Denotes a safety net price.
- **Authority required** indicates that prior approval is required from the relevant authority.
- **Note** provides additional information or restrictions on the use of the medication.

---

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### PREPARATIONS WHICH MAY BE PRESCRIBED FOR PATIENTS RECEIVING PALLIATIVE CARE

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<tr>
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<tbody>
<tr>
<td>5357Y</td>
<td>diazepam 2 mg tablet, 50</td>
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<td></td>
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<td>Valium RO</td>
</tr>
</tbody>
</table>

**Note**: Where consultation with a palliative care specialist or service has occurred, applications for increased repeats may be authorised.

### OXAZEPAM

**Authority required**

Initial supply, for up to 4 months, for a palliative care patient where anxiety is a problem

**Note**: No applications for increased repeats will be authorised.

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
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<th>No. of Rpts</th>
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<th>Brand Name and Manufacturer</th>
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<tbody>
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<td>oxazepam 15 mg tablet, 25</td>
<td>2</td>
<td>3</td>
<td>*9.24</td>
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<td>Mogadon VT</td>
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<td>5372R</td>
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<td>3</td>
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<td>10.39</td>
<td>Alepam 30 AF</td>
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<td>Serepax QA</td>
</tr>
</tbody>
</table>

**Note**: Where consultation with a palliative care specialist or service has occurred, applications for increased repeats may be authorised.

---

### HYPNOTICS AND SEDATIVES

**Benzodiazepine derivatives**

**NITRAZEPAM**

**Authority required**

Initial supply, for up to 4 months, for a palliative care patient where insomnia is a problem

**Note**: No applications for increased repeats will be authorised.

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<thead>
<tr>
<th>Code</th>
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<td>3</td>
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<td>11.61</td>
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<td></td>
<td></td>
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<td></td>
<td></td>
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<td>Mogadon VT</td>
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</tbody>
</table>

**NITRAZEPAM**

**Note**

Continuing supply for a palliative care patient where insomnia is a problem.
### TEMAZEPAM

**Authority required**

Initial supply, for up to 4 months, for a palliative care patient where insomnia is a problem

**Note**

No applications for increased repeats will be authorised.

<table>
<thead>
<tr>
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<td>.</td>
<td>*10.46</td>
<td>11.61</td>
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<td>.</td>
<td>Normison QA</td>
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**Authority required**

Continuing supply for a palliative care patient where insomnia is a problem

**Note**

Where consultation with a palliative care specialist or service has occurred, applications for increased repeats may be authorised.

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>Dispensed Price for Max. Qty $</th>
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<td>4.10</td>
<td>*12.94</td>
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<td>.</td>
<td>Normison QA</td>
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Items Available under Special Arrangements (Section 100)
Section 100 – Items Available under Special Arrangement

In addition to the drugs and medicinal preparations available under normal PBS arrangements listed in this Schedule, a number of drugs are also available as pharmaceutical benefits but are distributed under alternative arrangements where these are considered more appropriate.

These alternative arrangements are provided for under section 100 of the National Health Act 1953. Several programs exist for the provision of drugs as pharmaceutical benefits in this way and this section lists those drugs which are available under the following programs:

- Highly Specialised Drugs Program
- Botulinum Toxin Program
- Human Growth Hormone Program
- IVF/GIFT Program
- Opiate Dependence Treatment Program

Complete details concerning the availability of drugs as benefits under these programs may be obtained by telephoning the relevant contact number(s) shown in each section, or in certain cases, by referring to the telephone number provided for individual drugs listings.
Section 100 – Highly Specialised Drugs Program

The Australian Government provides funding for certain specialised medications under the Highly Specialised Drugs Program. Highly Specialised Drugs are medicines for the treatment of chronic conditions which, because of their clinical use or other special features, are restricted to supply through public and private hospitals having access to appropriate specialist facilities. To prescribe these drugs as pharmaceutical benefit items, medical practitioners are required to be affiliated with these specialist hospital units. A general practitioner or non-specialist hospital doctor may only prescribe Highly Specialised Drugs to provide maintenance therapy under the guidance of the treating specialist.

Benefits are available for the listed clinical indications only. There is no facility for individual patient approval for indications outside those listed.

To gain access to a Commonwealth funded drug under this program, a patient must attend a participating hospital and be a day admitted patient, a non-admitted patient or a patient on discharge, be under appropriate specialist medical care, meet the specific medical criteria and be an Australian resident in Australia (or other eligible person).

A patient will be required to pay a contribution for each supply of a highly specialised drug at a similar rate to the Pharmaceutical Benefits Scheme. Commonwealth subsidy is not available for hospital in-patients.

Reciprocal Health Care Agreement – Where a patient is entitled to be treated as an eligible person as a visitor from a country with which Australia has entered into a Reciprocal Health Care Agreement, the supply will be limited to the original prescription only. Repeat prescriptions for these patients are not permitted.

Private Hospitals – In addition to the above requirements, for Highly Specialised Drugs prescribed through private hospitals, claiming and approval of authority prescriptions is administered by Medicare Australia. Highly Specialised Drugs are authority required items. Medical practitioners must seek approval to prescribe these items as pharmaceutical benefits prior to their dispensing under the PBS. Approval of authority prescriptions by Medicare Australia may be obtained either by posting an Authority Prescription Form to Medicare Australia, or by using Medicare Australia’s Authority Freecall service (1800 888 333). Prescribers must quote the provider number of the hospital when applying. Not more than two months’ supply (one month’s supply in the case of Clozapine), with provision for up to 5 repeats, will be authorised. Prescriptions for Highly Specialised Drugs can be dispensed by an approved private hospital’s dispensary or by a community pharmacy.

The remuneration rates for Highly Specialised Drugs prescribed through private hospitals comprise the normal PBS ready-prepared dispensing fee plus a mark-up ascertained as follows:

- 10% for drugs with a price ex-manufacturer of less than $40;
- $4 for drugs with a price ex-manufacturer of between $40 and $100;
- 4% for drugs with a price ex-manufacturer of between $100.01 and $1000;
- $40 for drugs with a price ex-manufacturer of greater than $1000.

Public Hospitals – For Highly Specialised Drugs prescribed through public hospitals, claiming and access to the program is administered by the States/Territories Health Departments. Prescriptions for Highly Specialised Drugs can be dispensed by public hospital pharmacies.

If you would like further information about the Highly Specialised Drugs Program, please contact your pharmacy, Medicare Australia (Ph: 132 290) or the Australian Government adviser, the Highly Specialised Drugs Working Party Secretariat (Ph: (02) 6289 2331).
## Highly Specialised Drugs Program (Private Hospital)

### Blood and Blood Forming Organs

#### Antihaemorrhagics

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>Dispensed Price for Max. Qty $</th>
<th>Brand Name and Manufacturer</th>
</tr>
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</table>

#### Vitamin K and Other Hemostatics

**Other Systemic Hemostatics**

**Eltrombopag**

**Authority required**

**Initial (new patients)**

Initial treatment, as the sole PBS-subsidised thrombopoietin receptor agonist (TRA), of severe thrombocytopenia in an adult patient with severe chronic immune (idiopathic) thrombocytopenic purpura (ITP) who is:

1. Splenectomised and:
   a. has had an inadequate response to, or is intolerant to, corticosteroid therapy post splenectomy; and
   b. has had an inadequate response to, or is intolerant to, immunoglobulin therapy post splenectomy; or
2. Not splenectomised and:
   a. has had an inadequate response, or is intolerant to, corticosteroid therapy at a dose equivalent to 0.5-2 mg/kg/day of prednisone for at least 4-6 weeks; and
   b. has had an inadequate response, or is intolerant to, immunoglobulin therapy; and
   c. in whom splenectomy is contraindicated for medical reasons.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of initial application:

1. a platelet count of less than or equal to 20,000 million per L; or
2. a platelet count of 20-30,000 million per L, where the patient is experiencing significant bleeding or has a history of significant bleeding in this platelet range.

The authority application must be made in writing and must include:

1. a completed authority prescription form,
2. a signed patient acknowledgement,
3. a completed Idiopathic Thrombocytopenic Purpura Initial PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)],
4. a copy of a full blood count pathology report supporting the diagnosis of ITP, and
5. where the application is sought on the basis of a medical contraindication to surgery, a signed and dated letter from the clinician making this assessment which includes the date upon which the patient was assessed for surgery and the clinical grounds upon which surgery is contraindicated.

The full blood count must be no more than 1 month old at the time of application.

A maximum of 24 weeks of treatment with eltrombopag will be authorised under this criterion.

**Authority required**

**Initial (grandfather patients)**

Initial treatment, as the sole PBS-subsidised thrombopoietin receptor agonist (TRA), of severe thrombocytopenia in an adult patient with severe chronic immune (idiopathic) thrombocytopenic purpura (ITP) who was receiving treatment with eltrombopag prior to 1 November 2011 and in whom the criteria for initial treatment can be demonstrated to have been met at the time eltrombopag was commenced.

The authority application must be made in writing and must include:

1. a completed authority prescription form,
2. a signed patient acknowledgement,
3. a completed Idiopathic Thrombocytopenic Purpura Initial PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)], and
4. where the application is sought on the basis of a medical contraindication to surgery, a signed and dated letter from the clinician making this assessment which includes the date upon which the patient was assessed for surgery and the clinical grounds upon which surgery is contraindicated.

A maximum of 24 weeks of treatment with eltrombopag will be authorised under this criterion.

**Authority required**

Continuing therapy or re-initiation after a break in therapy

First period of PBS-subsidised continuing treatment or re-initiation of interrupted PBS-subsidised treatment, as the sole PBS-subsidised thrombopoietin receptor agonist (TRA), of severe thrombocytopenia in an adult patient with chronic immune (idiopathic) thrombocytopenic purpura (ITP) who has displayed a sustained platelet response to treatment with eltrombopag during the initial period of PBS-subsidised treatment.

For the purposes of this restriction, a sustained platelet response is defined as:
(a) use of rescue medication (corticosteroids or immunoglobulins) on no more than one occasion during the initial period of PBS-subsidised eltrombopag,

AND either of the following:

(b) a platelet count greater than or equal to 50,000 million per L on at least four (4) occasions, each at least one week apart;

OR

(c) a platelet count greater than 30,000 million per L and which is double the baseline (pre-treatment) platelet count on at least four (4) occasions, each at least one week apart.

Applications for the first period of continuing PBS-subsidised treatment or re-initiation of interrupted treatment must be made in writing and must include:

(1) a completed authority prescription form, and

(2) a completed Idiopathic Thrombocytopenic Purpura Continuing PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)], and

(3) copies of the platelet count pathology reports (unless previously provided for patients re-initiating therapy).

The most recent platelet count must be no more than one month old at the time of application.

A maximum of 24 weeks of treatment with eltrombopag will be authorised under this criterion.

Where fewer than 5 repeats are initially requested with the authority prescription, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be made by telephone.

**Authority required**

Second and subsequent applications for continuing therapy

Continuing treatment, as the sole PBS-subsidised thrombopoietin receptor agonist (TRA), of severe thrombocytopenia in an adult patient with chronic immune (idiopathic) thrombocytopenic purpura (ITP) who has previously received PBS-subsidised therapy with eltrombopag and who continues to display a response to treatment with eltrombopag.

For the purposes of this restriction, a continuing response to treatment with eltrombopag is defined as:

(a) use of rescue medication (corticosteroids or immunoglobulins) on no more than one occasion during the most recent 24 week period of PBS-subsidised treatment with eltrombopag,

AND either of the following:

(b) a platelet count greater than or equal to 50,000 million per L

OR

(c) a platelet count greater than 30,000 million per L and which is double the baseline platelet count.

Platelet counts must be no more than 1 month old at the time of application.

Authority applications for second and subsequent periods of continuing therapy may be made by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Note**

Eltrombopag is not PBS-subsidised as an alternative to splenectomy.

Any queries concerning the arrangements to prescribe eltrombopag may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authority to prescribe eltrombopag should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

Further prescribing information is on the Medicare Australia website at www.medicareaustralia.gov.au.

**Note**

Patients will be able to trial either eltrombopag and/or romiplostim within the initial 24 weeks treatment period. Patients who fail to demonstrate a response to treatment with either eltrombopag and/or romiplostim under the initial restriction will not be eligible to receive further PBS-subsidised treatment with either of these drugs.

No applications for increased repeats will be authorised.

**Note**

No applications for increased repeats will be authorised.

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
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<td>3070.76</td>
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</table>

ROMIPLOSTIM
Subsequently during the initial period of dose titration, authority applications for a single dose and up to 1 repeat may be made by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

The dose (microgram/kg/week) must be

Authority required

Initial (new patients)

Initial treatment, as the sole PBS-subsidised thrombopoietin receptor agonist (TRA), of severe thrombocytopenia in an adult patient with severe chronic immune (idiopathic) thrombocytopenic purpura (ITP) who is:

(1) Splenectomised and:

(a) has had an inadequate response to, or is intolerant to, corticosteroid therapy post splenectomy; and

(b) has had an inadequate response to, or is intolerant to, immunoglobulin therapy post splenectomy;

OR

(2) Not splenectomised and:

(a) has had an inadequate response, or is intolerant to, corticosteroid therapy at a dose equivalent to 0.5-2 mg/kg/day of prednisone for at least 4-6 weeks; and

(b) has had an inadequate response, or is intolerant to, immunoglobulin therapy; and

(c) in whom splenectomy is contraindicated for medical reasons.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of initial application:

(a) a platelet count of less than or equal to 20,000 million per L;

OR

(b) a platelet count of 20-30,000 million per L, where the patient is experiencing significant bleeding or has a history of significant bleeding in this platelet range.

The authority application must be made in writing and must include:

(1) a completed authority prescription form,

(2) a signed patient acknowledgement,

(3) a completed Idiopathic Thrombocytopenic Purpura Initial PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)],

(4) a copy of a full blood count pathology report supporting the diagnosis of ITP, and

(5) where the application is sought on the basis of a medical contraindication to surgery, a signed and dated letter from the clinician making this assessment which includes the date upon which the patient was assessed for surgery and the clinical grounds upon which surgery is contraindicated.

The full blood count must be no more than 1 month old at the time of application.

At the time of the written authority application, medical practitioners should request the appropriate quantity of vials of appropriate strength to provide sufficient drug for a single treatment at a dose of 1 microgram/kg. Up to 1 repeat may be requested with the initial written application. Subsequently during the initial period of dose titration, authority applications for a single dose and up to 1 repeat may be made by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). The dose (microgram/kg/week) must be provided at the time of application.

Once a patient’s dose has been stable for a period of 4 weeks, authority approvals for sufficient vials of appropriate strength based on the weight of the patient and dose (microgram/kg/week) for up to 4 weeks of treatment and up to 4 repeats may be granted, as long as the total period of treatment authorised under this restriction does not exceed 24 weeks.

Authority approval will not be given for doses of higher than 10 micrograms/kg/week

Authority required

Initial (grandfather patients)

Initial PBS-subsidised treatment, as the sole PBS-subsidised thrombopoietin receptor agonist (TRA), of severe thrombocytopenia in an adult patient with severe chronic immune (idiopathic) thrombocytopenic purpura (ITP) who was receiving treatment with romiplostim prior to 1 April 2011 and in whom the criteria for initial treatment can be demonstrated to have been met at the time romiplostim was commenced.

The authority application must be made in writing and must include:

(1) a completed authority prescription form,

(2) a signed patient acknowledgement,

(3) a completed Idiopathic Thrombocytopenic Purpura Initial PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)], and

(4) where the application is sought on the basis of a medical contraindication to surgery, a signed and dated letter from the clinician making this assessment which includes the date upon which the patient was assessed for surgery and the clinical grounds upon which surgery is contraindicated.

For patients whose dose of romiplostim had been stable for at least 4 weeks at the time of the initial application for PBS-subsidy, the medical practitioner should request sufficient number of vials based on the weight of the patient and dose (microgram/kg/week) to provide up to 4 weeks of treatment. Up to a maximum of 5 repeats may be authorised.

Where the patient is in the titration phase of treatment with romiplostim, medical practitioners should request the appropriate quantity of vials of appropriate strength to provide sufficient drug for a single treatment at a dose of 1 microgram/kg. Up to 1 repeat may be requested with the initial written application.

Subsequently during the initial period of dose titration, authority applications for a single dose and up to 1 repeat may be made by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). The dose (microgram/kg/week) must be provided at the time of application.
Once a patient’s dose has been stable for a period of 4 weeks, authority approvals for sufficient vials of appropriate strength based on the weight of the patient and dose (microgram/kg/week) for up to 4 weeks of treatment and up to 4 repeats may be granted, as long as the total period of treatment authorised under this restriction does not exceed 24 weeks.

Authority approval will not be given for doses of higher than 10 micrograms/kg/week

**Authority required**

Continuing therapy or re-initiation after a break in therapy

First period of PBS-subsidised continuing treatment or re-initiation of interrupted PBS-subsidised treatment, as the sole PBS-subsidised thrombopoietin receptor agonist (TRA), of severe thrombocytopenia in an adult patient with chronic immune (idiopathic) thrombocytopenic purpura (ITP) who has displayed a sustained platelet response to treatment with romiplostim during the initial period of PBS-subsidised treatment.

For the purposes of this restriction, a sustained platelet response is defined as:

(a) use of rescue medication (corticosteroids or immunoglobulins) on no more than one occasion during the initial period of PBS-subsidised romiplostim,

AND either of the following:

(b) a platelet count greater than or equal to 50,000 million per L on at least four (4) occasions, each at least one week apart;

OR

(c) a platelet count greater than 30,000 million per L and which is double the baseline (pre-treatment) platelet count on at least four (4) occasions, each at least one week apart.

Applications for the first period of continuing PBS-subsidised treatment or re-initiation of interrupted treatment must be made in writing and must include:

1. a completed authority prescription form, and
2. a completed Idiopathic Thrombocytopenic Purpura Continuing PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)], and
3. copies of the platelet count pathology reports (unless previously provided for patients re-initiating therapy).

The most recent platelet count must be no more than one month old at the time of application.

The medical practitioner should request sufficient number of vials of appropriate strength based on the weight of the patient and dose (microgram/kg/week) to provide 4 weeks of treatment. Up to a maximum of 5 repeats may be authorised.

Where fewer than 5 repeats are initially requested with the authority prescription, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be made by telephone.

Authority approval will not be given for doses of higher than 10 micrograms/kg/week

**Authority required**

Second and subsequent applications for continuing therapy

Continuing treatment, as the sole PBS-subsidised thrombopoietin receptor agonist (TRA), of severe thrombocytopenia in an adult patient with chronic immune (idiopathic) thrombocytopenic purpura (ITP) who has previously received PBS-subsidised therapy with romiplostim and who continues to display a response to treatment with romiplostim.

For the purposes of this restriction, a continuing response to treatment with romiplostim is defined as:

(a) use of rescue medication (corticosteroids or immunoglobulins) on no more than one occasion during the most recent 24 week period of PBS-subsidised treatment with romiplostim,

AND either of the following:

(b) a platelet count greater than or equal to 50,000 million per L

OR

(c) a platelet count greater than 30,000 million per L and which is double the baseline platelet count.

Platelet counts must be no more than 1 month old at the time of application.

Authority applications for second and subsequent periods of continuing therapy may be made by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

The medical practitioner should request sufficient number of vials of appropriate strength based on the weight of the patient and dose (microgram/kg/week) to provide 4 weeks of treatment. Up to a maximum of 5 repeats may be authorised.

Authority approval will not be given for doses of higher than 10 micrograms/kg/week

**Note**

Romiplostim is not PBS-subsidised as an alternative to splenectomy.

Any queries concerning the arrangements to prescribe romiplostim may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authority to prescribe romiplostim should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826
Further prescribing information is on the Medicare Australia website at www.medicareaustralia.gov.au.

**Note**
Patients will be able to trial either eltrombopag and/or romiplostim within the initial 24 weeks treatment period. Patients who fail to demonstrate a response to treatment with either eltrombopag and/or romiplostim under the initial restriction will not be eligible to receive further PBS-subsidised treatment with either of these drugs.

**Note**
Special Pricing Arrangements apply.

### Darbepoetin Alfa

**Authority required**
Treatment of anaemia requiring transfusion, defined as a haemoglobin level of less than 100 g per L, where intrinsic renal disease, as assessed by a nephrologist, is the primary cause of the anaemia

<table>
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<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
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<th>Premium $</th>
<th>Qty $</th>
<th>Brand Name and Manufacturer</th>
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### Epoetin Alfa

**Authority required**
Treatment of anaemia requiring transfusion, defined as a haemoglobin level of less than 100 g per L, where intrinsic renal disease, as assessed by a nephrologist, is the primary cause of the anaemia

<table>
<thead>
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<td>Eprex 10000 JC</td>
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<tr>
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<td>Eprex 1000 JC</td>
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**ANTIANEMIC PREPARATIONS**

**OTHER ANTIANEMIC PREPARATIONS**

*Other antianemic preparations*
## HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

<table>
<thead>
<tr>
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### EPOETIN BETA

**Authority required**

Treatment of anaemia requiring transfusion, defined as a haemoglobin level of less than 100 g per L, where intrinsic renal disease, as assessed by a nephrologist, is the primary cause of the anaemia.

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<td>6484G</td>
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<td>NeoRecormon RO</td>
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### EPOETIN LAMBDA

**Authority required**

Treatment of anaemia requiring transfusion, defined as a haemoglobin level of less than 100 g per L, where intrinsic renal disease, as assessed by a nephrologist, is the primary cause of the anaemia.

**Note**

Epoetin lambda should only be administered by the intravenous route.

<table>
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<tr>
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<td>9687W</td>
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<tr>
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### METHOXY POLYETHYLENE GLYCOL-EPOETIN BETA

**Authority required**

Treatment of anaemia requiring transfusion, defined as a haemoglobin level of less than 100 g per L, where intrinsic renal disease, as assessed by a nephrologist, is the primary cause of the anaemia.

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<tr>
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<th>Brand Name and Manufacturer</th>
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<td>*1388.40</td>
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<td>Code</td>
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CARDIOVASCULAR SYSTEM

<table>
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<tr>
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ANTIHYPERTENSIVES

Other antihypertensives

AMBRISENTAN

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 (new patients)

Clinical criteria:

Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent,

AND

Patient must have been assessed by a physician at a designated hospital,

AND

Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (IPAH) or anorexigen-induced PAH or hereditable PAH; OR

Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease,

AND

Patient must have a mean right atrial pressure of 8 mmHg or less as measured by right heart catheterisation (RHC); OR

Patient must have right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds,

AND

Patient must have failed to respond to 6 or more weeks of appropriate vasodilator treatment unless intolerance or a contraindication to such treatment exists,

AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

1. a completed authority prescription form; and
2. a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
   i. RHC composite assessment; and
   ii. ECHO composite assessment; and
   iii. 6 Minute Walk Test (6MWT); and
3. a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditable pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger’s physiology) are defined as follows:

i. mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or

ii. where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient’s baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

1. RHC plus ECHO composite assessments;
2. RHC composite assessment plus 6MWT;
3. RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

1. ECHO composite assessment plus 6MWT;
2. ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be...
conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Details of prior vasodilator treatment, including the dose and duration of treatment, must be provided at the time of application. Where the patient has an adverse event to a vasodilator or where vasodilator treatment is contraindicated, details of the nature of the adverse event or contraindication according to the Therapeutic Goods Administration (TGA) approved Product Information must also be provided with the application.

Response to prior vasodilator treatment is defined as follows:

For patients with 2 or more baseline tests, response to treatment is defined as 2 or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.

A maximum of 5 repeats may be requested.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term ‘PAH agents’ refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Note
Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Note
Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

Authority required
Pulmonary arterial hypertension (PAH)

Clinical criteria:
Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent,

AND

Patient must have been assessed by a physician at a designated hospital,

AND

Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH, and a mean right atrial pressure of greater than 8 mmHg, as measured by right heart catheterisation (RHC); OR

Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH, with right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds; OR

Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease and a mean right atrial pressure greater than 8 mmHg, as measured by RHC; OR

Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease with right ventricular function assessed by ECHO where a RHC cannot be performed on clinical grounds; OR

Patient must have WHO Functional Class IV idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH; OR

Patient must have WHO Functional Class IV pulmonary arterial hypertension secondary to connective tissue disease,
The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

1. a completed authority prescription form; and
2. a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
   (i) RHC composite assessment; and
   (ii) ECHO composite assessment; and
   (iii) 6 Minute Walk Test (6MWT); and
3. a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditary pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger’s physiology) are defined as follows:

1. mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or
2. where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient’s baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

1. RHC plus ECHO composite assessments;
2. RHC composite assessment plus 6MWT;
3. RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

1. ECHO composite assessment plus 6MWT;
2. ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats may be requested.

The term ‘PAH agents’ refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

**Note**

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.health.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

**Note**

Refer to the Department of Human Services website at www.health.gov.au for a list of designated hospitals.

**Authority required**

Pulmonary arterial hypertension (PAH)
For patients aged 3 (change or re-commencement of therapy for all patients)

Clinical criteria:

Patient must have idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease and must wish to re-commence PBS-subsidised therapy with this agent after a break in therapy and must have demonstrated a response to their most recent course of PBS-subsidised treatment with this agent; OR

Patient must have idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease and whose most recent course of PBS-subsidised treatment was with a PAH agent other than this agent,

AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and
(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form; and
(3) the results of the patient’s response to treatment with their last course of PBS-subsidised PAH agent.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats may be requested.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term ‘PAH agents’ refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Swapping between PAH agents:

Patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment with 1 of these 7 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent’s restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. New baselines may be submitted where the patient has failed to respond to their current treatment.

Eligible patients may only swap between PAH agents if they have not failed prior PBS-subsidised treatment with that agent.

For eligible patients, applications to swap between the 7 PAH agents must be made under the relevant initial treatment restriction. Patients should be assessed for response to the treatment they are ceasing at the time the application to swap therapy is being made. Patients who fail to demonstrate a response or for whom no assessment results are submitted with the application to swap therapy may not re-commence PBS-subsidised treatment with the drug they are ceasing.

Note

Applications for patients who wish to swap to an alternate PAH agent should be accompanied by the previously approved authority prescription, or remaining repeats, for the treatment the patient is ceasing.

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>Dispensed Price for Max. Qty $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>GPO Box 9826</td>
<td>HOBART TAS 7001</td>
<td>Note</td>
<td>Refer to the Department of Human Services website at <a href="http://www.humanservices.gov.au">www.humanservices.gov.au</a> for a list of designated hospitals.</td>
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</table>

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 or Initial 2 (new patients) or Initial 3 (change or re-commencement of therapy for all patients) or Continuing treatment (all patients) – balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this agent under the Initial 1 (new patients) restriction to complete a maximum of six months of treatment; OR
- Patient must have received insufficient therapy with this agent under the Initial 2 (new patients) restriction to complete a maximum of six months of treatment; OR
- Patient must have received insufficient therapy with this agent under the Initial 3 (change or re-commencement of therapy for all patients) restriction to complete a maximum of six months of treatment; OR
- Patient must have received insufficient therapy with this agent under the Continuing treatment (all patients) restriction to complete a maximum of six months of treatment,

AND

The treatment must be the sole PBS-subsidised PAH agent for this condition,

AND

The treatment must provide no more than the balance of up to six months treatment available under the above restrictions.

**Note**

Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authorisation under this criterion should be forwarded to:

Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826

GPO Box 9826
HOBART TAS 7001

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Continuing treatment (all patients)

**Clinical criteria:**

- Patient must have received approval for initial PBS-subsidised treatment with this agent,

AND

Patient must have been assessed by a physician from a designated hospital to have achieved a response to their most recent course of treatment with this agent,

AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

1. a completed authority prescription form; and
2. a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
   i. RHC composite assessment; and
   ii. ECHO composite assessment; and
   iii. 6 Minute Walk Test (6MWT).

Test requirements to establish response to treatment for continuation of treatment are as follows:

The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:

1. RHC plus ECHO composite assessments plus 6MWT;
2. RHC plus ECHO composite assessments;
3. RHC composite assessment plus 6MWT;
4. ECHO composite assessment plus 6MWT;
5. RHC composite assessment only;
### HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

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<td>2923.23</td>
<td>Volibris</td>
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**BOSENTAN**

**Authority required**

Pulmonary arterial hypertension (PAH)

**Treatment Phase: Initial 1 (new patients)**

**Clinical criteria:**

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent,

**AND**

- Patient must have been assessed by a physician at a designated hospital.

---

(A) ECHO composite assessment only.

The results of the same tests as conducted at baseline should be provided with each written continuing treatment application (i.e., every 6 months), except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application.

The test results provided with the application for continuing treatment must be no more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

- For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.
- For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.
- For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.
- For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

The assessment of the patient’s response to the first and subsequent 6 month courses of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Applications for continuing treatment with a PAH agent should be made prior to the completion of the 6 month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term ‘PAH agents’ refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

**Caution**

This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 3 months following cessation of therapy.

**Note**

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

**Note**

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</table>
| AND  | Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH; OR Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease, AND Patient must have a mean right atrial pressure of 8 mmHg or less as measured by right heart catheterisation (RHC); OR Patient must have right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds, AND Patient must have failed to respond to 6 or more weeks of appropriate vasodilator treatment unless intolerance or a contraindication to such treatment exists, AND The treatment must be the sole PBS-subsidised PAH agent for this condition. Applications for authorisation must be in writing and must include: (1) two completed authority prescription forms; and (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available: (i) RHC composite assessment; and (ii) ECHO composite assessment; and (iii) 6 Minute Walk Test (6MWT); and (3) a signed patient acknowledgement. Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows: (i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or (ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function. Test requirements to establish baseline for initiation of treatment are as follows: The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements. Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment: (1) RHC plus ECHO composite assessments; (2) RHC composite assessment plus 6MWT; (3) RHC composite assessment only. In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference: (1) ECHO composite assessment plus 6MWT; (2) ECHO composite assessment only. Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application. The test results provided must not be more than 2 months old at the time of application. Details of prior vasodilator treatment, including the dose and duration of treatment, must be provided at the time of application. Where the patient has an adverse event to a vasodilator or where vasodilator treatment is contraindicated, details of the nature of the adverse event or contraindication according to the Therapeutic Goods Administration (TGA) approved Product Information must also be provided with the application. Response to prior vasodilator treatment is defined as follows: For patients with 2 or more baseline tests, response to treatment is defined as 2 or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital. For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital. For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital. For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital. Approvals for the first authority prescription will be limited to 1 month of therapy with the 62.5 mg strength tablet, with the quantity approved...
based on the dosage recommendations in the TGA-approved Product Information. No repeats will be authorised for this prescription.

The second authority prescription may be written for either the 62.5 mg tablet or the 125 mg tablet strengths. Approvals for the second authority prescription will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term ‘PAH agents’ refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

**Note**

Where the 62.5 mg tablet strength is required for the second authority prescription, please contact the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) for further advice.

The approved second authority prescription will be returned to the prescriber by the Department of Human Services two weeks after the date of the approval of the first authority prescription, to allow for the uninterrupted completion of the six months initial treatment course. The Department of Human Services will contact prescribers prior to dispatch of the second authority prescription to confirm the tablet strength required for the patient.

**Note**

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

**Note**

Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 (new patients)

**Clinical criteria:**

Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent,

**AND**

Patient must have been assessed by a physician at a designated hospital.

**AND**

Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH, and a mean right atrial pressure of greater than 8 mmHg, as measured by right heart catheterisation (RHC); OR

Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH, with right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds; OR

Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension secondary to connective tissue disease and a mean right atrial pressure greater than 8 mmHg, as measured by RHC; OR

Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease with right ventricular function assessed by ECHO where a RHC cannot be performed on clinical grounds; OR

Patient must have WHO Functional Class IV idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH; OR

Patient must have WHO Functional Class IV pulmonary arterial hypertension secondary to connective tissue disease; OR

Patient must haveWHO Functional Class III or IV pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger’s physiology).

**AND**

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

1. two completed authority prescription forms; and

2. a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditable pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger’s physiology) are defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or
(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:
The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient’s baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments;
(2) RHC composite assessment plus 6MWT;
(3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

(1) ECHO composite assessment plus 6MWT;
(2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Approvals for the first authority prescription will be limited to 1 month of therapy with the 62.5 mg strength tablet, with the quantity approved based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information. No repeats will be authorised for this prescription.

The second authority prescription may be written for either the 62.5 mg tablet or the 125 mg tablet strengths. Approvals for the second authority prescription will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats.

The term ‘PAH agents’ refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Note
Where the 62.5 mg tablet strength is required for the second authority prescription, please contact the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) for further advice.

The approved second authority prescription will be returned to the prescriber by the Department of Human Services two weeks after the date of the approval of the first authority prescription, to allow for the uninterrupted completion of the six months initial treatment course. The Department of Human Services will contact prescribers prior to dispatch of the second authority prescription to confirm the tablet strength required for the patient.

Note
Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs

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GPO Box 9826
HOBART TAS 7001
For eligible patients, a submitted where the patient has failed to respond to their current treatment.

Clinical criteria:

Treatment Phase: Initial 3 (change or re-commencement of therapy for all patients)

- Authorised for this prescription.
- Approvals for the first authority prescription will be limited to 1 month of therapy with the 62.5 mg strength tablet, with the quantity approved.
- For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.
- For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.
- For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.
- Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease treatment. This means that no new baseline measurements will be necessary. New baselines may be conducted must be provided with the authority application.
- The approved second authority prescription will be returned to the prescriber by the Department of Human Services two weeks after the date of the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. New baselines may be conducted must be provided with the authority application.
- Response to a PAH agent is defined as follows:
- The treatment must be the sole PBS-subsidised PAH agent for this condition.
- Applications for authorisation must be in writing and must include:
  1. two completed authority prescription forms; and
  2. a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form; and
  3. the results of the patient's response to treatment with their last course of PBS-subsidised PAH agent.
- Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.
- The test results provided must not be more than 2 months old at the time of application.
- Response to a PAH agent is defined as follows:
- For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.
- For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.
- For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.
- For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.
- Approvals for the first authority prescription will be limited to 1 month of therapy with the 62.5 mg strength tablet, with the quantity approved.
- The second authority prescription may be written for either the 62.5 mg tablet or the 125 mg tablet strengths. Approvals for the second authority prescription will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information. No repeats will be authorised for this prescription.
- Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.
- The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.
- PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.
- Swapping between PAH agents:
- Patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment with 1 of these 7 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent’s restriction, irrespective of the severity of their disease at the time of application. It also means that no new baseline measurements will be necessary. New baselines may be submitted where the patient has failed to respond to their current treatment.
- Eligible patients may only swap between PAH agents if they have not failed prior PBS-subsidised treatment with that agent.
- For eligible patients, applications to swap between the 7 PAH agents must be made under the relevant initial treatment restriction. Patients should be assessed for response to the treatment they are ceasing at the time the application to swap therapy is being made. Patients who fail to demonstrate a response or for whom no assessment results are submitted with the application to swap therapy may not re-commence PBS-subsidised treatment with the drug they are ceasing.
- Note
- Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 3 (change or re-commencement of therapy for all patients)

Clinical criteria:

- Patient must have idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease or PAH associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger’s physiology) and must wish to re-commence PBS-subsidised therapy with this agent after a break in therapy and must have demonstrated a response to their most recent course of PBS-subsidised treatment with this agent; OR
- Patient must have idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease or PAH associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger’s physiology) and whose most recent course of PBS-subsidised treatment was with a PAH agent other than this agent,

AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

- (1) two completed authority prescription forms; and
- (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form; and
- (3) the results of the patient’s response to treatment with their last course of PBS-subsidised PAH agent.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

Approvals for the first authority prescription will be limited to 1 month of therapy with the 62.5 mg strength tablet, with the quantity approved. The second authority prescription may be written for either the 62.5 mg tablet or the 125 mg tablet strengths. Approvals for the second authority prescription will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information. No repeats will be authorised for this prescription.

The second authority prescription may be written for either the 62.5 mg tablet or the 125 mg tablet strengths. Approvals for the second authority prescription will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information. No repeats will be authorised for this prescription.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Swapping between PAH agents:

Patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment with 1 of these 7 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent’s restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. New baselines may be submitted where the patient has failed to respond to their current treatment.

Eligible patients may only swap between PAH agents if they have not failed prior PBS-subsidised treatment with that agent.

For eligible patients, applications to swap between the 7 PAH agents must be made under the relevant initial treatment restriction. Patients should be assessed for response to the treatment they are ceasing at the time the application to swap therapy is being made. Patients who fail to demonstrate a response or for whom no assessment results are submitted with the application to swap therapy may not re-commence PBS-subsidised treatment with the drug they are ceasing.

Note

Where the 62.5 mg tablet strength is required for the second authority prescription, please contact the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) for further advice.

The approved second authority prescription will be returned to the prescriber by the Department of Human Services two weeks after the date of the approval of the first authority prescription, to allow for the uninterrupted completion of the six months initial treatment course. The Department of
Applications for patients who wish to swap to an alternate PAH agent should be accompanied by the previously approved authority prescription, or remaining repeats, for the treatment the patient is ceasing.

Note

Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authorisation under this criterion should be forwarded to:

Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Note

Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.
HIGHERLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Qty | Brand Name and Manufacturer
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(1) a completed authority prescription form; and
(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

(i) RHC composite assessment; and
(ii) ECHO composite assessment; and
(iii) 6 Minute Walk Test (6MWT).

Test requirements to establish response to treatment for continuation of treatment are as follows:

The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments plus 6MWT;
(2) RHC plus ECHO composite assessments;
(3) RHC composite assessment plus 6MWT;
(4) ECHO composite assessment plus 6MWT;
(5) RHC composite assessment only;
(6) ECHO composite assessment only.

The results of the same tests as conducted at baseline should be provided with each written continuing treatment application (i.e., every 6 months), except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application.

The test results provided with the application for continuing treatment must be no more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

The assessment of the patient’s response to the first and subsequent 6 month courses of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Applications for continuing treatment with a PAH agent should be made prior to the completion of the 6 month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term ‘PAH agents’ refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Caution
This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 3 months following cessation of therapy.

Note
Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Note
Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

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**BOSENTAN**

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 (new patients)

**Clinical criteria:**

Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent,

AND

Patient must have been assessed by a physician at a designated hospital,

AND

Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH; OR

Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease,

AND

Patient must have a mean right atrial pressure of 8 mmHg or less as measured by right heart catheterisation (RHC); OR

Patient must have right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds,

AND

Patient must have failed to respond to 6 or more weeks of appropriate vasodilator treatment unless intolerance or a contraindication to such treatment exists,

AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) two completed authority prescription forms; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6 Minute Walk Test (6MWT); and

(3) a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditable pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient’s baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments;

(2) RHC composite assessment plus 6MWT;

(3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

(1) ECHO composite assessment plus 6MWT;

(2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Details of prior vasodilator treatment, including the dose and duration of treatment, must be provided at the time of application. Where the patient
HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

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has an adverse event to a vasodilator or where vasodilator treatment is contraindicated, details of the nature of the adverse event or contraindication according to the Therapeutic Goods Administration (TGA) approved Product Information must also be provided with the application.

Response to prior vasodilator treatment is defined as follows:

For patients with 2 or more baseline tests, response to treatment is defined as 2 or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

Approvals for the first authority prescription will be limited to 1 month of therapy with the 62.5 mg strength tablet, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information. No repeats will be authorised for this prescription.

The second authority prescription may be written for either the 62.5 mg tablet or the 125 mg tablet strengths. Approvals for the second authority prescription will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term ‘PAH agents’ refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

**Note**
Where the 62.5 mg tablet strength is required for the second authority prescription, please contact the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) for further advice.

The approved second authority prescription will be returned to the prescriber by the Department of Human Services two weeks after the date of the approval of the first authority prescription, to allow for the uninterrupted completion of the six months initial treatment course. The Department of Human Services will contact prescribers prior to dispatch of the second authority prescription to confirm the tablet strength required for the patient.

**Note**
Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs

Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

**Note**
Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

**Authority required**
Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 (new patients)

**Clinical criteria:**

Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent,

AND

Patient must have been assessed by a physician at a designated hospital,

AND

Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH, and a mean right atrial pressure of greater than 8 mmHg, as measured by right heart catheterisation (RHC); OR

Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH, with right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds; OR

Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease and a mean right atrial pressure greater than 8 mmHg, as measured by RHC; OR

Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease with right ventricular function.
assessed by ECHO where a RHC cannot be performed on clinical grounds; OR

- Patient must have WHO Functional Class IV idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH; OR
- Patient must have WHO Functional Class IV pulmonary arterial hypertension secondary to connective tissue disease; OR
- Patient must have WHO Functional Class III or IV pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger’s physiology), AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

1. two completed authority prescription forms; and
2. a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
   - (i) RHC composite assessment; and
   - (ii) ECHO composite assessment; and
   - (iii) 6 Minute Walk Test (6MWT); and
3. a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditable pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger’s physiology) are defined as follows:

1. mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or
2. where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient’s baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

1. RHC plus ECHO composite assessments;
2. RHC composite assessment plus 6MWT;
3. RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

1. ECHO composite assessment plus 6MWT;
2. ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Approvals for the first authority prescription will be limited to 1 month of therapy with the 62.5 mg strength tablet, with the quantity approved based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information. No repeats will be authorised for this prescription.

The second authority prescription may be written for either the 62.5 mg tablet or the 125 mg tablet strengths. Approvals for the second authority prescription will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats.

The term ‘PAH agents’ refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

**Note**
Where the 62.5 mg tablet strength is required for the second authority prescription, please contact the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) for further advice.

The approved second authority prescription will be returned to the prescriber by the Department of Human Services two weeks after the date of the approval of the first authority prescription, to allow for the uninterrupted completion of the six months initial treatment course. The Department of Human Services will contact prescribers prior to dispatch of the second authority prescription to confirm the tablet strength required for the patient.
Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Note
Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

Authority required
Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 3 (change or re-commencement of therapy for all patients)

Clinical criteria:

Patient must have idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease or PAH associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger’s physiology) and must wish to re-commence PBS-subsidised therapy with this agent after a break in therapy and must have demonstrated a response to their most recent course of PBS-subsidised treatment with this agent; OR

Patient must have idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease or PAH associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger’s physiology) and whose most recent course of PBS-subsidised treatment was with a PAH agent other than this agent;

AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) two completed authority prescription forms; and
(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form; and
(3) the results of the patient’s response to treatment with their last course of PBS-subsidised PAH agent.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

Approvals for the first authority prescription will be limited to 1 month of therapy with the 62.5 mg strength tablet, with the quantity approved based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information. No repeats will be authorised for this prescription.

The second authority prescription may be written for either the 62.5 mg tablet or the 125 mg tablet strengths. Approvals for the second authority prescription will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term ‘PAH agents’ refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Swapping between PAH agents:

Patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment with 1 of these 7 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that
patients may commence treatment with the alternate agent, subject to that agent’s restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. New baselines may be submitted where the patient has failed to respond to their current treatment.

Eligible patients may only swap between PAH agents if they have not failed prior PBS-subsidised treatment with that agent.

For eligible patients, applications to swap between the 7 PAH agents must be made under the relevant initial treatment restriction. Patients should be assessed for response to the treatment they are ceasing at the time the application to swap therapy is being made. Patients who fail to demonstrate a response or for whom no assessment results are submitted with the application to swap therapy may not re-commence PBS-subsidised treatment with the drug they are ceasing.

**Note**
Where the 62.5 mg tablet strength is required for the second authority prescription, please contact the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) for further advice.

The approved second authority prescription will be returned to the prescriber by the Department of Human Services two weeks after the date of the approval of the first authority prescription, to allow for the uninterrupted completion of the six months initial treatment course. The Department of Human Services will contact prescribers prior to dispatch of the second authority prescription to confirm the tablet strength required for the patient.

**Note**
Applications for patients who wish to swap to an alternate PAH agent should be accompanied by the previously approved authority prescription, or remaining repeats, for the treatment the patient is ceasing.

**Note**
Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

**Note**
Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

**Authority required**
Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 or Initial 2 (new patients) or Initial 3 (change or re-commencement of therapy for all patients) or Continuing treatment (all patients) – balance of supply

**Clinical criteria:**
Patient must have received insufficient therapy with this agent under the Initial 1 (new patients) restriction to complete a maximum of six months of treatment; OR
Patient must have received insufficient therapy with this agent under the Initial 2 (new patients) restriction to complete a maximum of six months of treatment; OR
Patient must have received insufficient therapy with this agent under the Initial 3 (change or re-commencement of therapy for all patients) restriction to complete a maximum of six months of treatment; OR
Patient must have received insufficient therapy with this agent under the Continuing treatment (all patients) restriction to complete a maximum of six months of treatment,

AND

The treatment must be the sole PBS-subsidised PAH agent for this condition,

AND

The treatment must provide no more than the balance of up to six months treatment available under the above restrictions.

**Note**
Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authorisation under this criterion should be forwarded to:

Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001
**Highly Specialised Drugs Program (Private Hospital)**

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### Authority Required

**Pulmonary arterial hypertension (PAH)**

**Treatment Phase:** Continuing treatment (all patients)

### Clinical Criteria:

- Patient must have received approval for initial PBS-subsidised treatment with this agent,
- **AND** Patient must have been assessed by a physician from a designated hospital to have achieved a response to their most recent course of treatment with this agent,
- **AND** The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

1. A completed authority prescription form; and
2. A completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
   - (i) RHC composite assessment; and
   - (ii) ECHO composite assessment; and
   - (iii) 6 Minute Walk Test (6MWT).

Test requirements to establish response to treatment for continuation of treatment are as follows:

- The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:
  1. RHC plus ECHO composite assessments plus 6MWT;
  2. RHC plus ECHO composite assessments;
  3. RHC composite assessment plus 6MWT;
  4. ECHO composite assessment plus 6MWT;
  5. RHC composite assessment only;
  6. ECHO composite assessment only.

The results of the same tests as conducted at baseline should be provided with each written continuing treatment application (i.e., every 6 months), except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application.

The test results provided with the application for continuing treatment must be no more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

- For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.
- For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.
- For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.
- For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

The assessment of the patient’s response to the first and subsequent 6 month courses of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Applications for continuing treatment with a PAH agent should be made prior to the completion of the 6 month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

### Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of...
HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

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**Note**
Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

**Authority required**
Pulmonary arterial hypertension (PAH)

Treatment Phase: Cessation of treatment (all patients)

**Clinical criteria:**

- Patient must have received approval for initial PBS-subsidised treatment with this agent,
  
  **AND**
  
  - Patient must have not responded to prior PBS-subsidised therapy with this agent,

  **AND**

  - The treatment must be for the purpose of gradual dose reduction prior to ceasing therapy,

  **AND**

  - The treatment must be the sole PBS-subsidised PAH agent for this condition.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment. Treatment beyond 1 month will not be approved.

**Caution**
This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 3 months following cessation of therapy.

**Note**
Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authorisation under this criterion should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

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**EPOPROSTENOL**

**Authority required**
Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 (new patients)

**Clinical criteria:**

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent,

  **AND**
  
  - Patient must have been assessed by a physician at a designated hospital,

  **AND**

  - Patient must have WHO Functional Class IV idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH; OR

  - Patient must have WHO Functional Class IV pulmonary arterial hypertension secondary to connective tissue disease,

  **AND**

  - The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditable pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger’s physiology) are defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or
(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient’s baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

1. RHC plus ECHO composite assessments;
2. RHC composite assessment plus 6MWT;
3. RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

1. ECHO composite assessment plus 6MWT;
2. ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats may be requested.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term ‘PAH agents’ refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Note
Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Note
Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.
The Department of Human Services has approved a patient's request to swap to an alternate PAH agent.

Clinical criteria:

Patient must have idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease and must wish to re-commence PBS-subsidised therapy with this agent; OR

Patient must have WHO Functional Class IV idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease and must have received prior treatment with a PBS-subsidised PAH agent other than this agent; OR

Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease and must have failed to respond to a prior PBS-subsidised PAH agent.

AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for patients who wish to swap to an alternate PAH agent must be made under the relevant initial treatment restriction. Patients should be assessed for response to the treatment they are ceasing at the time the application to swap therapy is being made. Patients who fail to demonstrate a response to PBS-subsidised treatment with that agent.

Note

Applications for patients who wish to swap to an alternate PAH agent should be accompanied by the previously approved authority prescription, or remaining repeats, for the treatment the patient is ceasing.

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Note Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

Note Pharmaceutical benefits that have the form epoprostenol sodium powder for I.V. infusion 1.5 mg (base) infusion administration set and pharmaceutical benefits that have the form epoprostenol 1.5 mg injection vial are equivalent for the purposes of substitution.

Note Pharmaceutical benefits that have the form epoprostenol sodium powder for I.V. infusion 500 micrograms (base) infusion administration set and pharmaceutical benefits that have the form epoprostenol 500 microgram injection vial are equivalent for the purposes of substitution.

Authority required
Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 (new patients) or Initial 2 (change or re-commencement of therapy for all patients) or Continuing treatment (all patients)
- balance of supply

Clinical criteria:
Patient must have received insufficient therapy with this agent under the Initial 1 (new patients) restriction to complete a maximum of six months of treatment; OR
Patient must have received insufficient therapy with this agent under the Initial 2 (change or re-commencement of therapy for all patients) restriction to complete a maximum of six months of treatment; OR
Patient must have received insufficient therapy with this agent under the Continuing treatment (all patients) restriction to complete a maximum of six months of treatment,

AND
The treatment must be the sole PBS-subsidised PAH agent for this condition,

AND
The treatment must provide no more than the balance of up to six months treatment available under the above restrictions.

Note Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authorisation under this criterion should be forwarded to:
Department of Human Services
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Note Pharmaceutical benefits that have the form epoprostenol sodium powder for I.V. infusion 1.5 mg (base) infusion administration set and pharmaceutical benefits that have the form epoprostenol 1.5 mg injection vial are equivalent for the purposes of substitution.

Note Pharmaceutical benefits that have the form epoprostenol sodium powder for I.V. infusion 500 micrograms (base) infusion administration set and pharmaceutical benefits that have the form epoprostenol 500 microgram injection vial are equivalent for the purposes of substitution.

Authority required
Pulmonary arterial hypertension (PAH)

Treatment Phase: Continuing treatment (all patients)

Clinical criteria:
Patient must have received approval for initial PBS-subsidised treatment with this agent,

AND
Patient must have been assessed by a physician from a designated hospital to have achieved a response to their most recent course of treatment with this agent,

AND
The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three
tests below, where available:
(i) RHC composite assessment; and
(ii) ECHO composite assessment; and
(iii) 6 Minute Walk Test (6MWT).

Test requirements to establish response to treatment for continuation of treatment are as follows:
The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:
(1) RHC plus ECHO composite assessments plus 6MWT;
(2) RHC plus ECHO composite assessments;
(3) RHC composite assessment plus 6MWT;
(4) ECHO composite assessment plus 6MWT;
(5) RHC composite assessment only;
(6) ECHO composite assessment only.

The results of the same tests as conducted at baseline should be provided with each written continuing treatment application
(i.e., every 6 months),
except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability
or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for
assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application.

The test results provided with the application for continuing treatment must be no more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:
For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of
disease, as assessed by a physician from a designated hospital.
For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or
improvement of disease, as assessed by a physician from a designated hospital.
For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or
improvement of disease, as assessed by a physician from a designated hospital.
For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement
of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in
the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

The assessment of the patient’s response to the first and subsequent 6 month courses of treatment should be made following the preceding 5
months of treatment, in order to allow sufficient time for a response to be demonstrated.

Applications for continuing treatment with a PAH agent should be made prior to the completion of the 6 month treatment course to ensure
continuity for those patients who respond to treatment, as assessed by the treating physician.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease
PBS-subsidised therapy with this agent.

The term ‘PAH agents’ refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and
macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue
disease, where the total lung capacity is less than 70% of predicted.

**Note**

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation
8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of
Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

**Note**

Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

**Note**

Pharmaceutical benefits that have the form epoprostenol sodium powder for I.V. infusion 1.5 mg (base) infusion administration set and
## Highly Specialised Drugs Program (Private Hospital)

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### Note
Pharmaceutical benefits that have the form epoprostenol 1.5 mg injection vial are equivalent for the purposes of substitution.

### Iloprost

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 (new patients)

**Clinical criteria:**

- Patient must not have received prior PBS-subsidised treatment with this agent,
- Patient must have been assessed by a physician at a designated hospital,
- Patient must have WHO Functional Class III drug-induced PAH,
- Patient must have a mean right atrial pressure of 8 mmHg or less as measured by right heart catheterisation (RHC); OR
- Patient must have right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds,
- Patient must have failed to respond to 6 or more weeks of appropriate vasodilator treatment unless intolerance or a contraindication to such treatment exists,
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

1. a completed authority prescription form; and
2. a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
   1. RHC composite assessment; and
   2. ECHO composite assessment; and
   3. 6 Minute Walk Test (6MWT); and
3. a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditable pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger’s physiology) are defined as follows:

1. mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or
2. where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient’s baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

1. RHC plus ECHO composite assessments;
2. RHC composite assessment plus 6MWT;
3. RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the
following test combinations, which are listed in descending order of preference:

(1) ECHO composite assessment plus 6MWT;

(2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Details of prior vasodilator treatment, including the dose and duration of treatment, must be provided at the time of application. Where the patient has an adverse event to a vasodilator or where vasodilator treatment is contraindicated, details of the nature of the adverse event or contraindication according to the Therapeutic Goods Administration (TGA) approved Product Information must also be provided with the application.

Response to prior vasodilator treatment is defined as follows:

For patients with 2 or more baseline tests, response to treatment is defined as 2 or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.

A maximum of 5 repeats may be requested.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term ‘PAH agents’ refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Note
Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

Note
Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

Note
Special Pricing Arrangements apply.

Authority required
Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 (new patients)

Clinical criteria:

Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent,

AND

Patient must have been assessed by a physician at a designated hospital,

AND

Patient must have WHO Functional Class III drug-induced PAH and a mean right atrial pressure greater than 8 mmHg, as measured by right heart catheterisation (RHC); OR

Patient must have WHO Functional Class III drug-induced PAH with right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed onclinical grounds; OR

Patient must have WHO Functional Class IV idiopathic pulmonary arterial hypertension (IPAH), or anorexigen-induced PAH or hereditable PAH; OR
Patient must have WHO Functional Class IV pulmonary arterial hypertension secondary to connective tissue disease; OR

Patient must have WHO Functional Class IV drug-induced PAH;

AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

1. a completed authority prescription form; and
2. a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
   i. RHC composite assessment; and
   ii. ECHO composite assessment; and
   iii. 6 Minute Walk Test (6MWT); and
3. a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditable pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger’s physiology) are defined as follows:

i. mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or

ii. where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient’s baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

1. RHC plus ECHO composite assessments;
2. RHC composite assessment plus 6MWT;
3. RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

1. ECHO composite assessment plus 6MWT;
2. ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats may be requested.

The term ‘PAH agents’ refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and PBS-subsidised therapy with this agent.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease or drug-induced PAH or hereditable PAH or PAH secondary to connective tissue disease or drug-induced PAH and must wish to re-commence PBS-subsidised therapy with this agent after a break in therapy and must have demonstrated a response to their most recent course of PBS-subsidised treatment with this agent; OR

Patient must have WHO Functional Class IV idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease and must have received prior treatment with a PBS-subsidised PAH agent other than this agent; OR

Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease and must have failed to respond to a prior PBS-subsidised PAH agent,

AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and
(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form; and
(3) the results of the patient’s response to treatment with their last course of PBS-subsidised PAH agent; and
(4) for WHO Functional Class III patients, where this is the first application for this agent, assessment details of the PBS-subsidised PAH agent they have failed to respond to.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats may be requested.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Swapping between PAH agents:

Patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment with 1 of these 7 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent’s restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. New baselines may be submitted where the patient has failed to respond to their current treatment.

Eligible patients may only swap between PAH agents if they have not failed prior PBS-subsidised treatment with that agent.

For eligible patients, applications to swap between the 7 PAH agents must be made under the relevant initial treatment restriction. Patients should be assessed for response to the treatment they are ceasing at the time the application to swap therapy is being made. Patients who fail to demonstrate a response or for whom no assessment results are submitted with the application to swap therapy may not re-commence PBS-subsidised treatment with the drug they are ceasing.

Applications for patients who wish to swap to an alternate PAH agent should be accompanied by the previously approved authority prescription, or remaining repeats, for the treatment the patient is ceasing.
Note
Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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HOBART TAS 7001

Note
Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

Note
Special Pricing Arrangements apply.

Authority required
Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 or Initial 2 (new patients) or Initial 3 (change or re-commencement of therapy for all patients) or Continuing treatment (all patients) – balance of supply

Clinical criteria:
Patient must have received insufficient therapy with this agent under the Initial 1 (new patients) restriction to complete a maximum of six months of treatment; OR
Patient must have received insufficient therapy with this agent under the Initial 2 (new patients) restriction to complete a maximum of six months of treatment; OR
Patient must have received insufficient therapy with this agent under the Initial 3 (change or re-commencement of therapy for all patients) restriction to complete a maximum of six months of treatment; OR
Patient must have received insufficient therapy with this agent under the Continuing treatment (all patients) restriction to complete a maximum of six months of treatment,

AND
The treatment must be the sole PBS-subsidised PAH agent for this condition,

AND
The treatment must provide no more than the balance of up to six months treatment available under the above restrictions.

Note
Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written applications for authorisation under this criterion should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Note
Special Pricing Arrangements apply.

Authority required
Pulmonary arterial hypertension (PAH)

Treatment Phase: Continuing treatment (all patients)

Clinical criteria:
Patient must have received approval for initial PBS-subsidised treatment with this agent,

AND
Patient must have been assessed by a physician from a designated hospital to have achieved a response to their most recent course of treatment with this agent,

AND
The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
(i) RHC composite assessment; and
(ii) ECHO composite assessment; and
(iii) 6 Minute Walk Test (6MWT).

Test requirements to establish response to treatment for continuation of treatment are as follows:

The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:
(1) RHC plus ECHO composite assessments plus 6MWT;
(2) RHC plus ECHO composite assessments;
(3) RHC composite assessment plus 6MWT;
(4) ECHO composite assessment plus 6MWT;
(5) RHC composite assessment only;
(6) ECHO composite assessment only.

The results of the same tests as conducted at baseline should be provided with each written continuing treatment application (i.e., every 6 months), except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application.

The test results provided with the application for continuing treatment must be no more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:
For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital. For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.
For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.
For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

Note
Special Pricing Arrangements apply.
MACITENTAN

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 (new patients)

Clinical criteria:

Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent,

AND

Patient must have been assessed by a physician at a designated hospital,

AND

Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH; OR

Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease,

AND

Patient must have a mean right atrial pressure of 8 mmHg or less as measured by right heart catheterisation (RHC); OR

Patient must have right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds,

AND

Patient must have failed to respond to 6 or more weeks of appropriate vasodilator treatment unless intolerance or a contraindication to such treatment exists,

AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6 Minute Walk Test (6MWT); and

(3) a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditable pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with congenital systemic-to-pulmonary shunt (including Eisenmenger’s physiology) are defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient’s baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments;

(2) RHC composite assessment plus 6MWT;

(3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

(1) ECHO composite assessment plus 6MWT;

(2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Details of prior vasodilator treatment, including the dose and duration of treatment, must be provided at the time of application. Where the patient has an adverse event to a vasodilator or where vasodilator treatment is contraindicated, details of the nature of the adverse event or contraindication according to the Therapeutic Goods Administration (TGA) approved Product Information must also be provided with the
Response to prior vasodilator treatment is defined as follows:

For patients with 2 or more baseline tests, response to treatment is defined as 2 or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as an RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.

A maximum of 5 repeats may be requested.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

**Note**

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

**Note**

Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 (new patients)

Clinical criteria:

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, AND
- Patient must have been assessed by a physician at a designated hospital, AND
- Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (IPAH), or anorexigen-induced PAH or heritable PAH, and a mean right atrial pressure of greater than 8 mmHg, as measured by right heart catheterisation (RHC); OR
- Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (IPAH), or anorexigen-induced PAH or heritable PAH, with right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds; OR
- Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease and a mean right atrial pressure greater than 8 mmHg, as measured by RHC; OR
- Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease with right ventricular function assessed by ECHO where a RHC cannot be performed on clinical grounds; OR
- Patient must have WHO Functional Class IV idiopathic pulmonary arterial hypertension (IPAH), or anorexigen-induced PAH or heritable PAH; OR
- Patient must have WHO Functional Class IV pulmonary arterial hypertension secondary to connective tissue disease; OR
- Patient must have WHO Functional Class III or IV pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger’s physiology), AND
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:
Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Qty $ | Brand Name and Manufacturer
---|---|---|---|---|---|---

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6 Minute Walk Test (6MWT); and

(3) a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditable pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger’s physiology) are defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

1. RHC plus ECHO composite assessments;
2. RHC composite assessment plus 6MWT;
3. RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

1. ECHO composite assessment plus 6MWT;
2. ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats may be requested.

The term ‘PAH agents’ refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

**Note**

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

**Note**

Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 3 (change or re-commencement of therapy for all patients)

**Clinical criteria:**
Department of Human Services

Applications for authority to prescribe should be forwarded to: Human Services website at www.humanservices.gov.au

Eligible patients may only swap between PAH agents if they have not failed prior PBS-subsidised treatment with that agent.

Patient must have idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease or PAH associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger’s physiology) and whose most recent course of PBS-subsidised treatment was with the same agent; OR

AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form; and

(3) the results of the patient’s response to treatment with their last course of PBS-subsidised PAH agent.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats may be requested.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term ‘PAH agents’ refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Swapping between PAH agents:

Patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment with 1 of these 7 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent’s restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. New baselines may be submitted where the patient has failed to respond to their current treatment.

Eligible patients may only swap between PAH agents if they have not failed prior PBS-subsidised treatment with that agent.

For eligible patients, applications to swap between the 7 PAH agents must be made under the relevant initial treatment restriction. Patients should be assessed for response to the treatment they are ceasing at the time the application to swap therapy is being made. Patients who fail to demonstrate a response or for whom no assessment results are submitted with the application to swap therapy may not re-commence PBS-subsidised treatment with the drug they are ceasing.

Note

Applications for patients who wish to swap to an alternate PAH agent should be accompanied by the previously approved authority prescription, or remaining repeats, for the treatment the patient is ceasing.

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
**HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)**

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<tr>
<th>Code</th>
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<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
<th>Premium $</th>
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| HOBART TAS 7001 | Note Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals. Authority required Pulmonary arterial hypertension (PAH) Treatment Phase: Initial 1 or Initial 2 (new patients) or Initial 3 (change or re-commencement of therapy for all patients) or Continuing treatment (all patients) – balance of supply Clinical criteria: Patient must have received insufficient therapy with this agent under the Initial 1 (new patients) restriction to complete a maximum of six months of treatment; OR Patient must have received insufficient therapy with this agent under the Initial 2 (new patients) restriction to complete a maximum of six months of treatment; OR Patient must have received insufficient therapy with this agent under the Initial 3 (change or re-commencement of therapy for all patients) restriction to complete a maximum of six months of treatment; OR Patient must have received insufficient therapy with this agent under the Continuing treatment (all patients) restriction to complete a maximum of six months of treatment, AND The treatment must be the sole PBS-subsidised PAH agent for this condition, AND The treatment must provide no more than the balance of up to six months treatment available under the above restrictions. Note Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Written applications for authorisation under this criterion should be forwarded to: Department of Human Services Prior Written Approval of Complex Drugs Reply Paid 9826 GPO Box 9826 HOBART TAS 7001 Authority required Pulmonary arterial hypertension (PAH) Treatment Phase: Continuing treatment (all patients) Clinical criteria: Patient must have received approval for initial PBS-subsidised treatment with this agent, AND Patient must have been assessed by a physician from a designated hospital to have achieved a response to their most recent course of treatment with this agent. AND The treatment must be the sole PBS-subsidised PAH agent for this condition. Applications for authorisation must be in writing and must include: (1) a completed authority prescription form; and (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available: (i) RHC composite assessment; and (ii) ECHO composite assessment; and (iii) 6 Minute Walk Test (6MWT). Test requirements to establish response to treatment for continuation of treatment are as follows: The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment: (1) RHC plus ECHO composite assessments plus 6MWT; (2) RHC plus ECHO composite assessments; (3) RHC composite assessment plus 6MWT; (4) ECHO composite assessment plus 6MWT; (5) RHC composite assessment only; (6) ECHO composite assessment only.
The results of the same tests as conducted at baseline should be provided with each written continuing treatment application (i.e., every 6 months), except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application.

The test results provided with the application for continuing treatment must be no more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

The assessment of the patient's response to the first and subsequent 6 month courses of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Applications for continuing treatment with a PAH agent should be made prior to the completion of the 6 month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

**Caution**

This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 3 months following cessation of therapy.

**Note**

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

**Note**

Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

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**SILDENAFIL**

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 (new patients)

**Clinical criteria:**

Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent,

AND

Patient must have been assessed by a physician at a designated hospital,

AND

Patient must have WHO Functional Class III Idiopathic pulmonary arterial hypertension (IPAH) or anorexigen-induced PAH or hereditable PAH; OR

Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease,
AND Patient must have a mean right atrial pressure of 8 mmHg or less as measured by right heart catheterisation (RHC); OR

AND Patient must have right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds,

AND Patient must have failed to respond to 6 or more weeks of appropriate vasodilator treatment unless intolerance or a contraindication to such treatment exists,

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6 Minute Walk Test (6MWT); and

(3) a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditable pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger’s physiology) are defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient’s baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments;

(2) RHC composite assessment plus 6MWT;

(3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

(1) ECHO composite assessment plus 6MWT;

(2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Details of prior vasodilator treatment, including the dose and duration of treatment, must be provided at the time of application. Where the patient has an adverse event to a vasodilator or where vasodilator treatment is contraindicated, details of the nature of the adverse event or contraindication according to the Therapeutic Goods Administration (TGA) approved Product Information must also be provided with the application.

Response to prior vasodilator treatment is defined as follows:

For patients with 2 or more baseline tests, response to treatment is defined as 2 or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.

A maximum of 5 repeats may be requested.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease
The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

**Note**
Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
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HOBART TAS 7001

**Note**
Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

**Authority required**
Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 (new patients)

**Clinical criteria:**

Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent,

AND

Patient must have been assessed by a physician at a designated hospital,

AND

Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH, and a mean right atrial pressure of greater than 8 mmHg, as measured by right heart catheterisation (RHC); OR

Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH, with right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds; OR

Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease and a mean right atrial pressure greater than 8 mmHg, as measured by RHC; OR

Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease with right ventricular function assessed by ECHO where a RHC cannot be performed on clinical grounds,

AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6 Minute Walk Test (6MWT); and

(3) a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditable pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order:

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>Dispensed Price for Max. Qty $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
</table>
order, for the purposes of initiation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments;
(2) RHC composite assessment plus 6MWT;
(3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

(1) ECHO composite assessment plus 6MWT;
(2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats may be requested.

The term ‘PAH agents’ refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Note
Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Note
Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

Authority required
Pulmonary arterial hypertension (PAH)
Treatment Phase: Initial 3 (change or re-commencement of therapy for all patients)

Clinical criteria:
Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease and must wish to re-commence PBS-subsidised therapy with this agent after a break in therapy and must have demonstrated a response to their most recent course of PBS-subsidised treatment with this agent; OR

Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease and whose most recent course of PBS-subsidised treatment was with a PAH agent other than this agent, AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and
(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form; and
(3) the results of the patient’s response to treatment with their last course of PBS-subsidised PAH agent.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:
For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or
improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats may be requested.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Swapping between PAH agents:

Patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment with 1 of these 7 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. New baselines may be submitted where the patient has failed to respond to their current treatment.

Eligible patients may only swap between PAH agents if they have not failed prior PBS-subsidised treatment with that agent.

For eligible patients, applications to swap between the 7 PAH agents must be made under the relevant initial treatment restriction. Patients should be assessed for response to the treatment they are ceasing at the time the application to swap therapy is being made. Patients who fail to demonstrate a response or for whom no assessment results are submitted with the application to swap therapy may not re-commence PBS-subsidised treatment with the drug they are ceasing.

*Note*

Applications for patients who wish to swap to an alternate PAH agent should be accompanied by the previously approved authority prescription, or remaining repeats, for the treatment the patient is ceasing.

*Note*

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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*Note*

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*Authority required*

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 or Initial 2 (new patients) or Initial 3 (change or re-commencement of therapy for all patients) or Continuing treatment (all patients) - balance of supply

Clinical criteria:

Patient must have received insufficient therapy with this agent under the Initial 1 (new patients) restriction to complete a maximum of six months of treatment; OR

Patient must have received insufficient therapy with this agent under the Initial 2 (new patients) restriction to complete a maximum of six months of treatment; OR

Patient must have received insufficient therapy with this agent under the Initial 3 (change or re-commencement of therapy for all patients) restriction to complete a maximum of six months of treatment; OR

Patient must have received insufficient therapy with this agent under the Continuing treatment (all patients) restriction to complete a maximum of six months of treatment,

AND

The treatment must be the sole PBS-subsidised PAH agent for this condition,

AND
HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

The treatment must provide no more than the balance of up to six months treatment available under the above restrictions.

**Note**

Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authorisation under this criterion should be forwarded to:

Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Continuing treatment (all patients)

**Clinical criteria:**

Patient must have received approval for initial PBS-subsidised treatment with this agent,

AND

Patient must have been assessed by a physician from a designated hospital to have achieved a response to their most recent course of treatment with this agent,

AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

1. a completed authority prescription form; and
2. a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
   i. RHC composite assessment; and
   ii. ECHO composite assessment; and
   iii. 6 Minute Walk Test (6MWT).

Test requirements to establish response to treatment for continuation of treatment are as follows:

The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:

1. RHC plus ECHO composite assessments plus 6MWT;
2. RHC plus ECHO composite assessments;
3. RHC composite assessment plus 6MWT;
4. ECHO composite assessment plus 6MWT;
5. RHC composite assessment only;
6. ECHO composite assessment only.

The results of the same tests as conducted at baseline should be provided with each written continuing treatment application (i.e., every 6 months), except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application.

The test results provided with the application for continuing treatment must be no more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

The assessment of the patient’s response to the first and subsequent 6 month courses of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Applications for continuing treatment with a PAH agent should be made prior to the completion of the 6 month treatment course to ensure
Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

**Note**

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

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Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

**Note**

Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

**TADALAFIL**

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 (new patients)

**Clinical criteria:**

Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent,

AND

Patient must have been assessed by a physician at a designated hospital,

AND

Patient must have WHO Functional Class III Idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH; OR

Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease,

AND

Patient must have a mean right atrial pressure of 8 mmHg or less as measured by right heart catheterisation (RHC); OR

Patient must have right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds,

AND

Patient must have failed to respond to 6 or more weeks of appropriate vasodilator treatment unless intolerance or a contraindication to such treatment exists,

AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

1. a completed authority prescription form; and
2. a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
   1. RHC composite assessment; and
   2. ECHO composite assessment; and
   3. 6 Minute Walk Test (6MWT); and
3. a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditable pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger’s physiology) are defined as...
HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

follows:

(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient’s baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments;

(2) RHC composite assessment plus 6MWT;

(3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

(1) ECHO composite assessment plus 6MWT;

(2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Details of prior vasodilator treatment, including the dose and duration of treatment, must be provided at the time of application. Where the patient has an adverse event to a vasodilator or where vasodilator treatment is contraindicated, details of the nature of the adverse event or contraindication according to the Therapeutic Goods Administration (TGA) approved Product Information must also be provided with the application.

Response to prior vasodilator treatment is defined as follows:

For patients with 2 or more baseline tests, response to treatment is defined as 2 or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.

A maximum of 5 repeats may be requested.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Note

Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

Authority required

Pulmonary arterial hypertension (PAH)
HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Treatment Phase: Initial 2 (new patients)

Clinical criteria:

Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent,

AND

Patient must have been assessed by a physician at a designated hospital,

AND

Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH, with a mean right atrial pressure greater than 8 mmHg, as measured by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds; OR

Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension secondary to connective tissue disease and a mean right atrial pressure greater than 8 mmHg, as measured by RHC; OR

Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease with right ventricular function assessed by ECHO where a RHC cannot be performed on clinical grounds,

AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6 Minute Walk Test (6MWT); and

(3) a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditable pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger’s physiology) are defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient’s baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments;

(2) RHC composite assessment plus 6MWT;

(3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

(1) ECHO composite assessment plus 6MWT;

(2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats may be requested.

The term ‘PAH agents’ refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalaflit, and macitentan.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.
HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

<table>
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**Note**

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**Note**
Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 3 (change or re-commencement of therapy for all patients)

**Clinical criteria:**

Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or heritable PAH or PAH secondary to connective tissue disease and must wish to re-commence PBS-subsidised therapy with this agent after a break in therapy and must have demonstrated a response to their most recent course of PBS-subsidised treatment with this agent: OR

Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or heritable PAH or PAH secondary to connective tissue disease and whose most recent course of PBS-subsidised treatment was with a PAH agent other than this agent, AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form; and

(3) the results of the patient’s response to treatment with their last course of PBS-subsidised PAH agent.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats may be requested.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term ‘PAH agents’ refers to bosentan monohydrate, iloprost trometamol, epoprostol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Swapping between PAH agents:

Patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment with 1 of these 7 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent’s restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. New baselines may be submitted where the patient has failed to respond to their current treatment.

Eligible patients may only swap between PAH agents if they have not failed prior PBS-subsidised treatment with that agent.

For eligible patients, applications to swap between the 7 PAH agents must be made under the relevant initial treatment restriction. Patients should...
be assessed for response to the treatment they are ceasing at the time the application to swap therapy is being made. Patients who fail to demonstrate a response or for whom no assessment results are submitted with the application to swap therapy may not re-commence PBS-subsidised treatment with the drug they are ceasing.

**Note**
Applications for patients who wish to swap to an alternate PAH agent should be accompanied by the previously approved authority prescription, or remaining repeats, for the treatment the patient is ceasing.

**Note**
Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

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**Note**
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**Authority required**
Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 or Initial 2 (new patients) or Initial 3 (change or re-commencement of therapy for all patients) or Continuing treatment (all patients) – balance of supply

**Clinical criteria:**
Patient must have received insufficient therapy with this agent under the Initial 1 (new patients) restriction to complete a maximum of six months of treatment; OR
Patient must have received insufficient therapy with this agent under the Initial 2 (new patients) restriction to complete a maximum of six months of treatment; OR
Patient must have received insufficient therapy with this agent under the Initial 3 (change or re-commencement of therapy for all patients) restriction to complete a maximum of six months of treatment; OR
Patient must have received insufficient therapy with this agent under the Continuing treatment (all patients) restriction to complete a maximum of six months of treatment,

**AND**
The treatment must be the sole PBS-subsidised PAH agent for this condition,

**AND**
The treatment must provide no more than the balance of up to six months treatment available under the above restrictions.

**Note**
Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authorisation under this criterion should be forwarded to:
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**Authority required**
Pulmonary arterial hypertension (PAH)

Treatment Phase: Continuing treatment (all patients)

**Clinical criteria:**
Patient must have received approval for initial PBS-subsidised treatment with this agent,

**AND**
Patient must have been assessed by a physician from a designated hospital to have achieved a response to their most recent course of treatment with this agent.

**AND**
The treatment must be the sole PBS-subsidised PAH agent for this condition.
Applications for authorisation must be in writing and must include:

1. a completed authority prescription form; and
2. a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
   i. RHC composite assessment; and
   ii. ECHO composite assessment; and
   iii. 6 Minute Walk Test (6MWT).

Test requirements to establish response to treatment for continuation of treatment are as follows:

The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:

1. RHC plus ECHO composite assessments plus 6MWT;
2. RHC plus ECHO composite assessments;
3. RHC composite assessment plus 6MWT;
4. ECHO composite assessment plus 6MWT;
5. RHC composite assessment only;
6. ECHO composite assessment only.

The results of the same tests as conducted at baseline should be provided with each written continuing treatment application (i.e., every 6 months), except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application.

The test results provided with the application for continuing treatment must be no more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

The assessment of the patient’s response to the first and subsequent 6 month courses of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Applications for continuing treatment with a PAH agent should be made prior to the completion of the 6 month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term ‘PAH agents’ refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

**Note**

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

**Note**

Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.
<table>
<thead>
<tr>
<th>Code</th>
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<th>Premium $</th>
<th>Qty $</th>
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</table>

Dispensed Price for Max. Qty
## SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS

### PITUITARY AND HYPOTHALAMIC HORMONES AND ANALOGUES

#### HYPOTHALAMIC HORMONES

*Somatostatin and analogues*

<table>
<thead>
<tr>
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<th>Dispensed Price for Max. Qty $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
</table>

**LANREOTIDE**

**Authority required**

Acromegaly

**Clinical criteria:**

The condition must be active,

AND

Patient must have persistent elevation of mean growth hormone levels of greater than 2.5 micrograms per litre,

AND

The treatment must be after failure of other therapy including dopamine agonists; OR

The treatment must be as interim treatment while awaiting the effects of radiotherapy and where treatment with dopamine agonists has failed; OR

The treatment must be in a patient who is unfit for or unwilling to undergo surgery and where radiotherapy is contraindicated,

AND

The treatment must cease in a patient treated with radiotherapy if there is biochemical evidence of remission (normal IGF1) after lanreotide has been withdrawn for at least 4 weeks (8 weeks after the last dose),

AND

The treatment must cease if IGF1 is not lower after 3 months of treatment.

In a patient treated with radiotherapy, lanreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission.

**Authority required**

Functional carcinoid tumour

**Clinical criteria:**

The condition must be causing intractable symptoms,

AND

Patient must have experienced on average over 1 week, 3 or more episodes per day of diarrhoea and/or flushing, which persisted despite the use of anti-histamines, anti-serotonin agents and anti-diarrhoea agents,

AND

Patient must be one in whom surgery or antineoplastic therapy has failed or is inappropriate,

AND

The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 3 months’ therapy at a dose of 120 mg every 28 days.

Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.

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<tr>
<th>Code</th>
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</thead>
</table>

- 6425E lanreotide 120 mg injection, 1 syringe
- 6423C lanreotide 60 mg injection, 1 syringe
- 6424D lanreotide 90 mg injection, 1 syringe

**LANREOTIDE**

**Authority required**

Acromegaly

**Clinical criteria:**

The condition must be active,

AND

Patient must have persistent elevation of mean growth hormone levels of greater than 2.5 micrograms per litre,
The treatment must be after failure of other therapy including dopamine agonists; OR
The treatment must be as interim treatment while awaiting the effects of radiotherapy and where treatment with dopamine agonists has failed; OR
The treatment must be in a patient who is unfit for or unwilling to undergo surgery and where radiotherapy is contraindicated,

AND

The treatment must cease in a patient treated with radiotherapy if there is biochemical evidence of remission (normal IGF1) after lanreotide has been withdrawn for at least 4 weeks (6 weeks after the last dose),

AND

The treatment must cease if IGF1 is not lower after 3 months of treatment.

In a patient treated with radiotherapy, lanreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission.

6332G lanreotide 30 mg injection: modified release [1 x 30 mg vial] (&) inert substance diluent [1 x 2 mL ampoule], 1 pack

$1546.76

Sandostatin LAR IS

OCTREOTIDE

Authority required

Acromegaly

Clinical criteria:
The condition must be controlled with octreotide immediate release injections, AND
The treatment must cease in a patient treated with radiotherapy if there is biochemical evidence of remission (normal IGF1) after octreotide has been withdrawn for at least 4 weeks (8 weeks after the last dose), AND
The treatment must cease if IGF1 is not lower after 3 months of treatment.

In a patient treated with radiotherapy, octreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission

Authority required

Functional carcinoid tumour

Clinical criteria:
Patient must have achieved symptom control on octreotide immediate release injections, AND
The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 3 months' therapy at a dose of 30 mg every 28 days and having allowed adequate rescue therapy with octreotide immediate release injections.

Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.

Authority required

Vasoactive intestinal peptide secreting tumour (VIPoma)

Clinical criteria:
Patient must have achieved symptom control on octreotide immediate release injections, AND
The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 3 months' therapy at a dose of 30 mg every 28 days and having allowed adequate rescue therapy with octreotide immediate release injections.

Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.

6426F octreotide 10 mg injection: modified release [1 x 10 mg vial] (&) inert substance diluent [1 x 2.5 mL syringe], 1 pack

$2660.48

Sandostatin LAR NV

OCTREOTIDE

Authority required

Active acromegaly in a patient with persistent elevation of mean growth hormone levels of greater than 2.5 micrograms per litre AND
(a) after failure of other therapy including dopamine agonists; or
(b) as interim treatment while awaiting the effects of radiotherapy and where treatment with dopamine agonists has failed; or
(c) if the patient is unfit for or unwilling to undergo surgery and where radiotherapy is contraindicated.
In a patient treated with radiotherapy, treatment must cease if there is biochemical evidence of remission (normal IGF1) after octreotide has been withdrawn for at least 4 weeks. Octreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission.

Treatment must cease if IGF1 is not lower after 3 months treatment at a dose of 100 micrograms 3 times daily

Authority required

Functional carcinoid tumour or vasoactive intestinal peptide secreting tumour (VIPoma) causing intractable symptoms. The patient must have experienced on average over 1 week, 3 or more episodes per day of diarrhoea and/or flushing, which persisted despite the use of anti-histamines, anti-serotonin agents and anti-diarrhoea agents, and surgery or antineoplastic therapy must have failed or be inappropriate.

Treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 2 months' therapy. Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.

6228T  octreotide 100 microgram/mL injection, 5 x 1 mL ampoules  18  11  ..  *1283.14  a  Hospira Pty Limited  HH  a  Octreotide (SUN) ZF  a  Octreotide MaxRx GQ  a  Sandostatin 0.1 NV

6227R  octreotide 50 microgram/mL injection, 5 x 1 mL ampoules  18  11  ..  *650.62  a  Hospira Pty Limited  HH  a  Octreotide (SUN) ZF  a  Octreotide MaxRx GQ  a  Sandostatin 0.05 NV

6229W  octreotide 500 microgram/mL injection, 5 x 1 mL ampoules  18  11  ..  *6241.24  a  Hospira Pty Limited  HH  a  Octreotide (SUN) ZF  a  Octreotide MaxRx GQ  a  Sandostatin 0.5 NV

CALCIUM HOMEOSTASIS

ANTI-PARATHYROID AGENTS

Other anti-parathyroid agents

CINACALCET

Authority required

Management, including initiation and stabilisation, by a nephrologist, of a patient with chronic kidney disease on dialysis who has sustained secondary hyperparathyroidism with iPTH of at least 50 pmol per L, not responding to conventional therapy

Authority required

Management, including initiation and stabilisation, by a nephrologist, of a patient with chronic kidney disease on dialysis who has sustained secondary hyperparathyroidism with iPTH of at least 15 pmol per L and less than 50 pmol per L AND an (adjusted) serum calcium concentration at least 2.6 mmol per L, not responding to conventional treatment

Note

During the titration phase, intact PTH should be monitored 4 weekly (measured at least 12 hours post dose) and dose titrated until an appropriate iPTH concentration is achieved. During the titration phase, approval will be limited to sufficient supply for 4 weeks treatment at a time, with doses between 30 and 180 mg per day according to the patient’s response and tolerability.

During the maintenance phase, approval will be limited to provide sufficient quantity for 4 weeks treatment up to a maximum of 6 months supply for doses between 30 and 180 mg per day according to the patient’s response and tolerability. Intact PTH should be monitored quarterly (measured at least 12 hours post dose) and dose adjusted as necessary to maintain an appropriate iPTH concentration.

“Sustained” means the abnormality was detected on at least 2 blood samples collected over a period of 2 to 4 months.

Note

Special Pricing Arrangements apply.

9625N  cinacalcet 30 mg tablet, 28  2  5  ..  *408.12  Sensipar  AN

9626P  cinacalcet 60 mg tablet, 28  2  5  ..  *809.48  Sensipar  AN

9627Q  cinacalcet 90 mg tablet, 28  2  5  ..  *1204.52  Sensipar  AN
### HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

#### ANTIINFECTIVES FOR SYSTEMIC USE

**ANTIBACTERIALS FOR SYSTEMIC USE**

**Macrolides**

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty</th>
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<th>Dispensed Price for Max. Qty</th>
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</thead>
<tbody>
<tr>
<td>6221K</td>
<td><strong>AZITHROMYCIN</strong> Authority required Prophylaxis against Mycobacterium avium complex infections in HIV-positive patients with CD4 cell counts of less than 75 per cubic millimetre</td>
<td>600 mg tablet, 8</td>
<td>2</td>
<td>5</td>
<td>..</td>
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</tbody>
</table>

**CLARITHROMYCIN** Authority required Treatment of Mycobacterium avium complex infections

<table>
<thead>
<tr>
<th>Code</th>
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</tr>
</thead>
<tbody>
<tr>
<td>6151R</td>
<td>clarithromycin 250 mg tablet, 100</td>
<td>250 mg tablet, 100</td>
<td>1</td>
<td>2</td>
<td>..</td>
</tr>
<tr>
<td>6152T</td>
<td>clarithromycin 500 mg tablet, 100</td>
<td>500 mg tablet, 100</td>
<td>1</td>
<td>2</td>
<td>..</td>
</tr>
</tbody>
</table>

**ANTIMYCOBACTERIALS**

**DRUGS FOR TREATMENT OF TUBERCULOSIS**

**Antibiotics**

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
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<th>No. of Rpts</th>
<th>Premium Qty</th>
<th>Dispensed Price for Max. Qty</th>
</tr>
</thead>
<tbody>
<tr>
<td>6195C</td>
<td><strong>RIFABUTIN</strong> Authority required Prophylaxis against Mycobacterium avium complex infections in HIV-positive patients with CD4 cell counts of less than 75 per cubic millimetre</td>
<td>150 mg capsule, 30</td>
<td>4</td>
<td>5</td>
<td>..</td>
</tr>
</tbody>
</table>

**ANTIVIRALS FOR SYSTEMIC USE**

**DIRECT ACTING ANTIVIRALS**

**Nucleosides and nucleotides excl. reverse transcriptase inhibitors**

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
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<th>Dispensed Price for Max. Qty</th>
</tr>
</thead>
<tbody>
<tr>
<td>6247T</td>
<td><strong>CIDOFOVIR</strong> Authority required Treatment of cytomegalovirus retinitis in patients with AIDS</td>
<td>375 mg/5 mL injection, 1 x 5 mL vial</td>
<td>4</td>
<td>3</td>
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</table>

**GANCICLOVIR** Authority required Cytomegalovirus retinitis in severely immunocompromised patients

<table>
<thead>
<tr>
<th>Code</th>
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<th>Dispensed Price for Max. Qty</th>
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</thead>
<tbody>
<tr>
<td>6136Y</td>
<td><strong>GANCICLOVIR</strong> Authority required Prophylaxis of cytomegalovirus disease in bone marrow transplant patients at risk of cytomegalovirus disease</td>
<td>500 mg injection, 5 x 500 mg vials</td>
<td>2</td>
<td>1</td>
<td>..</td>
</tr>
</tbody>
</table>

**VALACICLOVIR** Authority required Prophylaxis of cytomegalovirus (CMV) infection and disease following renal transplantation in patients at risk of CMV disease

<table>
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<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
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<th>No. of Rpts</th>
<th>Premium Qty</th>
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<tbody>
<tr>
<td>6280M</td>
<td><strong>VALACICLOVIR</strong> Authority required Prophylaxis of cytomegalovirus (CMV) infection and disease following renal transplantation in patients at risk of CMV disease</td>
<td>500 mg tablet, 100</td>
<td>5</td>
<td>2</td>
<td>..</td>
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</tbody>
</table>

\[a\] Valaciclovir RBX RA
\[a\] Valaciclovir AS
## HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

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<tbody>
<tr>
<td>6357N</td>
<td>Valganciclovir Authority required</td>
<td>2</td>
<td>5</td>
<td>..</td>
<td>Valcyte RO</td>
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<tr>
<td>9675F</td>
<td>Valganciclovir 50 mg/mL oral liquid: powder for, 100 mL</td>
<td>11</td>
<td>5</td>
<td>..</td>
<td>Valcyte RO</td>
</tr>
</tbody>
</table>

### Phosphonic acid derivatives

**FOSCARNET**

*Authority required*

- Treatment of cytomegalovirus retinitis in patients with AIDS
- Treatment of aciclovir-resistant herpes simplex virus infection in immunocompromised patients with HIV infection

6134W  
FOSCARNET SODIUM I.V. infusion 24 mg per mL, 250 mL bottle, 6  
1  1  ..  1224.26  Foscavir IX

### Protease inhibitors

**ATAZANAVIR**

*Authority required*

- HIV infection
  
  **Clinical criteria:**
  
  Patient must be antiretroviral treatment naive,
  
  AND
  
  The treatment must be in combination with other antiretroviral agents.

*Authority required*

- HIV infection
  
  **Clinical criteria:**
  
  Patient must have previously received PBS-subsidised therapy for HIV infection,
  
  AND
  
  The treatment must be in combination with other antiretroviral agents.

6451M  
atazanavir 150 mg capsule, 60  
2  5  ..  *1090.58  Reyataz BQ

6452N  
atazanavir 200 mg capsule, 60  
2  5  ..  *1438.52  Reyataz BQ

9614B  
atazanavir 300 mg capsule, 30  
2  5  ..  *1090.58  Reyataz BQ

**BOCEPREVIR**

*Authority required*

- Chronic genotype 1 hepatitis C infection
  
  **Clinical criteria:**
  
  Patient must have compensated liver disease,
  
  AND
  
  Patient must have received no more than one prior treatment with interferon alfa or peginterferon alfa for hepatitis C,
  
  AND
  
  The treatment must be in combination with peginterferon alfa and ribavirin,
  
  AND
  
  The treatment must be limited to a maximum duration of 32 weeks in patients without hepatic cirrhosis who were partial responders or relapers to the prior course of interferon based therapy for hepatitis C; OR
  
  The treatment must be limited to a maximum duration of 44 weeks in patients without hepatic cirrhosis who were null responders to the prior course of interferon based therapy for hepatitis C; OR
The treatment must be limited to a maximum duration of 44 weeks for all patients with hepatic cirrhosis,

AND

The treatment must cease after the first 8 weeks of boceprevir treatment if plasma HCV RNA is detectable by an HCV RNA qualitative assay at treatment week 12,

AND

The treatment must cease after the first 20 weeks of boceprevir treatment if plasma HCV RNA is detectable by an HCV RNA qualitative assay at treatment week 24.

Population criteria:
Patient must be 18 years or older,

AND

Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

Treatment criteria:
Must be treated in an accredited treatment centre.

Chronic genotype 1 hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient’s medical records.

Patients who have received prior treatment with an NS3/4A protease inhibitor are not eligible to receive PBS-subsidised boceprevir, except where the patient has developed an intolerance to the other NS3/4A protease inhibitor of a severity necessitating permanent treatment withdrawal.

Details of the intolerance must be documented in the patient’s medical records.

For patients without hepatic cirrhosis who were partial responders or relapers to the prior course of interferon based therapy, a maximum of 7 repeats may be prescribed.

For patients without hepatic cirrhosis who were null responders to the prior course of interferon based therapy, a maximum of 10 repeats may be prescribed.

For patients with hepatic cirrhosis, a maximum of 10 repeats may be prescribed.

Authority required
Chronic genotype 1 hepatitis C infection

Clinical criteria:
Patient must have compensated liver disease,

AND

Patient must not have received prior interferon alfa or peginterferon alfa treatment for hepatitis C,

AND

The treatment must be in combination with peginterferon alfa and ribavirin,

AND

The treatment must be limited to a maximum duration of 24 weeks in patients without hepatic cirrhosis; OR

The treatment must be limited to a maximum duration of 44 weeks in patients with hepatic cirrhosis,

AND

The treatment must cease after the first 20 weeks of boceprevir treatment if plasma HCV RNA is detectable by an HCV RNA qualitative assay at treatment week 24.

Population criteria:
Patient must be 18 years or older,

AND

Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

Treatment criteria:
Must be treated in an accredited treatment centre.

Evidence of chronic genotype 1 hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient’s medical records.

Patients who have received prior treatment with an NS3/4A protease inhibitor are not eligible to receive PBS-subsidised boceprevir, except where the patient has developed an intolerance to the other NS3/4A protease inhibitor of a severity necessitating permanent treatment withdrawal.

Details of the intolerance must be documented in the patient’s medical records.

For patients without hepatic cirrhosis, a maximum of 5 repeats may be prescribed.

For patients with hepatic cirrhosis, a maximum of 10 repeats may be prescribed.

Note
No increase in the maximum quantity or number of units may be authorised.

Note
Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for
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<tbody>
<tr>
<td>2435E</td>
<td>Boceprevir 200 mg capsule, 336 capsules</td>
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<td>3966.76</td>
<td>Victrelis MK</td>
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<tr>
<td>9581G</td>
<td>darunavir 150 mg tablet, 240</td>
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<td>5</td>
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<td>1095.47</td>
<td>Prezista JC</td>
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<tr>
<td>5000E</td>
<td>darunavir 600 mg tablet, 60</td>
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<td>5</td>
<td>..</td>
<td>*2144.18</td>
<td>Prezista JC</td>
</tr>
<tr>
<td>10000H</td>
<td>darunavir 800 mg tablet, 30</td>
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<td>5</td>
<td>..</td>
<td>*1445.04</td>
<td>Prezista JC</td>
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<tr>
<td>6454Q</td>
<td>fosamprenavir 50 mg/mL oral liquid, 225 mL</td>
<td>8</td>
<td>5</td>
<td>..</td>
<td>*851.72</td>
<td>Telzir VI</td>
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<tr>
<td>6453P</td>
<td>fosamprenavir 700 mg tablet, 60</td>
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<td>5</td>
<td>..</td>
<td>*795.42</td>
<td>Telzir VI</td>
</tr>
</tbody>
</table>

**DARUNAVIR**

**Authority required**

Treatment of HIV infection, in addition to optimised background therapy in combination with other antiretroviral agents, and co-administered with 100 mg ritonavir twice daily in an antiretroviral experienced patient who, after at least one antiretroviral regimen, has experienced virological failure or clinical failure or genotypic resistance.

Virological failure is defined as a viral load greater than 400 copies per mL on two consecutive occasions, while clinical failure is linked to emerging signs and symptoms of progressing HIV infection or treatment-limiting toxicity.

**Clinical criteria:**

- The treatment must be in addition to optimised background therapy,
- The treatment must be in combination with other antiretroviral agents,
- The treatment must be co-administered with 100 mg ritonavir,
- Patient must have experienced virological failure or clinical failure or genotypic resistance after at least one antiretroviral regimen,
- Patient must not have demonstrated darunavir resistance associated mutations detected on resistance testing.

**FOSAMPRENAVIR**

**Authority required**

HIV infection

**Clinical criteria:**

- Patient must be antiretroviral treatment naive,
- The treatment must be in combination with other antiretroviral agents.

**Authority required**

HIV infection

**Clinical criteria:**

- Patient must have previously received PBS-subsidised therapy for HIV infection,
- The treatment must be in combination with other antiretroviral agents.
## HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

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<tr>
<td></td>
<td>INDINAVIR</td>
<td>Authority required</td>
<td>HIV infection</td>
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**TELAPREVIR**

**Authority required**

Chronic genotype 1 hepatitis C infection

**Clinical criteria:**

Patient must have compensated liver disease,

**AND**

Patient must not have received prior treatment with interferon alfa or peginterferon alfa for hepatitis C,

**AND**

The treatment must be in combination with peginterferon alfa and ribavirin,

**AND**

The treatment must be limited to a maximum duration of 12 weeks,

**AND**

The treatment must cease if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is greater than 1000 IU/mL.

**Population criteria:**

Patient must be 18 years or older,

**AND**

Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

**Treatment criteria:**

Must be treated in an accredited treatment centre.

Evidence of chronic genotype 1 hepatitis C infection (repeatedly anti-HCV positive and HCV RNA positive) must be documented in the patient’s medical records.

Patients who have received prior treatment with an NS3/4A protease inhibitor are not eligible to receive PBS-subsidised telaprevir, except where the patient has developed an intolerance to the other NS3/4A protease inhibitor of a severity necessitating permanent treatment withdrawal. Details of the intolerance must be documented in the patient’s medical records.

**Authority required**

Chronic genotype 1 hepatitis C infection

**Clinical criteria:**

Patient must have compensated liver disease,

**AND**

Patient must have received prior treatment with interferon alfa or peginterferon alfa for hepatitis C,

**AND**

The treatment must be in combination with peginterferon alfa and ribavirin,

**AND**

The treatment must be limited to a maximum duration of 12 weeks,

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**Treatment criteria:**

Must be treated in an accredited treatment centre.

Evidence of chronic genotype 1 hepatitis C infection (repeatedly anti-HCV positive and HCV RNA positive) must be documented in the patient’s medical records.

Patients who have received prior treatment with an NS3/4A protease inhibitor are not eligible to receive PBS-subsidised telaprevir, except where the patient has developed an intolerance to the other NS3/4A protease inhibitor of a severity necessitating permanent treatment withdrawal. Details of the intolerance must be documented in the patient’s medical records.

**Note**

No increase in the maximum quantity or number of units may be authorised.
<table>
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<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
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**Nucleoside and nucleotide reverse transcriptase inhibitors**

**ABACAVIR**
- **Authority required**
- Treatment Phase: Initial
- Clinical criteria:
  - Patient must be antiretroviral treatment naive,
  - The treatment must be in combination with other antiretroviral agents.

**ADEFOVIR DIPIVOXIL**
- **Authority required**
- Chronic hepatitis B in a patient without cirrhosis who has failed antihepadnaviral therapy and who satisfies all of the following criteria:
  - Repeatedly elevated serum ALT levels while on concurrent antihepadnaviral therapy of greater than or equal to 6 months duration in conjunction with documented chronic hepatitis B infection; or
  - Repeatedly elevated HBV DNA levels one log greater than the nadir value or failure to achieve a 1 log reduction in HBV DNA within 3 months, whilst on previous antihepadnaviral therapy except in patients with evidence of poor compliance
- Chronic hepatitis B in a patient with cirrhosis who has failed antihepadnaviral therapy and who has detectable HBV DNA.
- Persons with Child’s class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy
- Note: Patients may receive treatment in combination with lamivudine but not with other PBS-subsidised antihepadnaviral therapy.

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**DIDANOSINE**

**Authority required**

HIV infection

Treatment Phase: Initial

**Clinical criteria:**

Patient must be antiretroviral treatment naive,

AND

The treatment must be in combination with other antiretroviral agents.

**Authority required**

HIV infection

Treatment Phase: Continuing

**Clinical criteria:**

Patient must have previously received PBS-subsidised therapy for HIV infection,

AND

The treatment must be in combination with other antiretroviral agents.

**EMTRICITABINE**

**Authority required**

HIV infection

Treatment Phase: Initial

**Clinical criteria:**

Patient must be antiretroviral treatment naive,

AND

The treatment must be in combination with other antiretroviral agents.

**Authority required**

HIV infection

Treatment Phase: Continuing

**Clinical criteria:**

Patient must have previously received PBS-subsidised therapy for HIV infection,

AND

The treatment must be in combination with other antiretroviral agents.

**ENTECAVIR**

**Authority required**

Chronic hepatitis B in a patient without cirrhosis who has failed lamivudine and who satisfies all of the following criteria:

(a) Repeatedly elevated serum ALT levels while on concurrent antihepadnaviral therapy of greater than or equal to 6 months duration in conjunction with documented chronic hepatitis B infection; or

(b) Repeatedly elevated HBV DNA levels one log greater than the nadir value or failure to achieve a 1 log reduction in HBV DNA within 3 months, whilst on previous antihepadnaviral therapy except in patients with evidence of poor compliance

**Authority required**

Chronic hepatitis B in a patient with cirrhosis who has failed lamivudine and who has detectable HBV DNA.

Persons with Child’s class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy

**Note**

PBS-subsidised entecavir monohydrate must be used as monotherapy.
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**ENTECAVIR**

**Authority required**

Chronic hepatitis B in a patient without cirrhosis who satisfies all of the following criteria:

1. Elevated HBV DNA levels - greater than 20,000 IU/mL (100,000 copies/mL) if HBeAg positive, or greater than 2,000 IU/mL (10,000 copies/mL) if HBeAg negative - in conjunction with documented chronic hepatitis B infection;
2. Evidence of chronic liver injury as determined by:
   a. Confirmed elevated serum ALT; or
   b. Liver biopsy

**Note**

PBS-subsidised entecavir monohydrate must be used as monotherapy.

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
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**LAMIVUDINE**

**Authority required**

HIV infection

**Clinical criteria:**

- The treatment must be antiretroviral treatment naive,
- The treatment must be in combination with other antiretroviral agents.

**Authority required**

HIV infection

**Clinical criteria:**

- Patient must have previously received PBS-subsidised therapy for HIV infection,
- The treatment must be in combination with other antiretroviral agents.

**Authority required**

Chronic hepatitis B in a patient without cirrhosis who satisfies all of the following criteria:

1. Elevated HBV DNA levels - greater than 20,000 IU/mL (100,000 copies/mL) if HBeAg positive, or greater than 2,000 IU/mL (10,000 copies/mL) if HBeAg negative - in conjunction with documented chronic hepatitis B infection;
2. Evidence of chronic liver injury as determined by:
   a. Confirmed elevated serum ALT; or
   b. Liver biopsy

**Note**

Persons with Child’s class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy.
## HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

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<td>The treatment must be in combination with other antiretroviral agents.</td>
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<td>(1) Elevated HBV DNA levels - greater than 20,000 IU/mL (100,000 copies/mL) if HBeAg positive, or greater than 2,000 IU/mL (10,000 copies/mL) if HBeAg negative - in conjunction with documented hepatitis B infection;</td>
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<td>(2) Evidence of chronic liver injury as determined by:</td>
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<td>(a) Confirmed elevated serum ALT; or</td>
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<td>(b) Liver biopsy</td>
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<td>Persons with Child’s class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy</td>
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</table>
Clinical criteria:
Patient must have previously received PBS-subsidised therapy for HIV infection,
AND
The treatment must be in combination with other antiretroviral agents.

Authority required
Chronic hepatitis B

Clinical criteria:
Patient must not have cirrhosis,
AND
Patient must be nucleoside analogue naive,
AND
Patient must have elevated HBV DNA levels greater than 20,000 IU/mL (100,000 copies/mL) if HBeAg positive, in conjunction with documented hepatitis B infection; OR
Patient must have elevated HBV DNA levels greater than 2,000 IU/mL (10,000 copies/mL) if HBeAg negative, in conjunction with documented hepatitis B infection,
AND
Patient must have evidence of chronic liver injury determined by: (i) confirmed elevated serum ALT; or (ii) liver biopsy,
AND
The treatment must be the sole PBS-subsidised therapy for this condition.

Note
Patients may receive treatment in combination with lamivudine but not with other PBS-subsidised antihepadnaviral therapy.

Authority required
Chronic hepatitis B

Clinical criteria:
Patient must have cirrhosis,
AND
Patient must be nucleoside analogue naive,
AND
Patient must have detectable HBV DNA,
AND
The treatment must be the sole PBS-subsidised therapy for this condition.

Note
Patients may receive treatment in combination with lamivudine but not with other PBS-subsidised antihepadnaviral therapy.

Authority required
Chronic hepatitis B

Clinical criteria:
Patient must have cirrhosis,
AND
Patient must have failed antihepadnaviral therapy,
AND
Patient must have repeatedly elevated serum ALT levels while on concurrent antihepadnaviral therapy of greater than or equal to 6 months duration, in conjunction with documented chronic hepatitis B infection; OR
Patient must have repeatedly elevated HBV DNA levels one log greater than the nadir value or failure to achieve a 1 log reduction in HBV DNA within 3 months whilst on previous antihepadnaviral therapy, except in patients with evidence of poor compliance.

Note
Patients may receive treatment in combination with lamivudine but not with other PBS-subsidised antihepadnaviral therapy.

Authority required
Chronic hepatitis B

Clinical criteria:
Patient must have cirrhosis,
AND
Patient must have failed antihepadnaviral therapy, AND
Patient must have detectable HBV DNA.
Persons with Child’s class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy.

Note
Patients may receive treatment in combination with lamivudine but not with other PBS-subsidised antihepadnaviral therapy.

6358P tenofovir disoproxil fumarate 300 mg tablet, 30

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<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
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ZIDOVUDINE

Authority required
HIV infection
Treatment Phase: Initial
Clinical criteria:
Patient must be antiretroviral treatment naive,
AND
The treatment must be in combination with other antiretroviral agents.

Authority required
HIV infection
Treatment Phase: Continuing
Clinical criteria:
Patient must have previously received PBS-subsidised therapy for HIV infection,
AND
The treatment must be in combination with other antiretroviral agents.

6153W zidovudine 100 mg capsule, 100

6154X zidovudine 250 mg capsule, 40

6155Y zidovudine 50 mg/5 mL oral liquid, 200 mL

Non-nucleoside reverse transcriptase inhibitors

EFAVIRENZ

Authority required
HIV infection
Treatment Phase: Initial
Clinical criteria:
Patient must be antiretroviral treatment naive,
AND
The treatment must be in combination with other antiretroviral agents.

Authority required
HIV infection
Treatment Phase: Continuing
Clinical criteria:
Patient must have previously received PBS-subsidised therapy for HIV infection,
AND
The treatment must be in combination with other antiretroviral agents.

9618F efavirenz 200 mg tablet, 90

6372J efavirenz 30 mg/mL oral liquid, 180 mL

6356M efavirenz 600 mg tablet, 30

ETRAVIRINE

Authority required
### HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

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**Treatment of HIV infection, in addition to optimised background therapy in combination with other antiretroviral agents in an antiretroviral experienced patient who, after each of at least three different antiretroviral regimens that have included one drug from at least 3 different antiretroviral classes, has experienced virological failure or clinical failure or genotypic resistance.**

Virological failure is defined as a viral load greater than 400 copies per mL on two consecutive occasions, while clinical failure is linked to emerging signs and symptoms of progressing HIV infection or treatment-limiting toxicity.

| 5062K | etravirine 200 mg tablet, 60 | 2 | 5 | .. | 1279.76 | Intelence JC |

### NEVIRAPINE

**Authority required**

HIV infection

**Clinical criteria:**

Patient must be antiretroviral treatment naive,

AND

The treatment must be in combination with other antiretroviral agents.

| 9571R | nevirapine 10 mg/mL oral liquid, 240 mL | 10 | 5 | .. | 1396.76 | Viramune BY |
| 6215D | nevirapine 200 mg tablet, 60 | 2 | 5 | .. | 481.28 | Nevipin GN |

### NEVIRAPINE

**Authority required**

HIV infection

**Clinical criteria:**

Patient must have been stabilised on nevirapine immediate release,

AND

The treatment must be in combination with other antiretroviral agents.

| 1129K | nevirapine 400 mg tablet: modified release, 30 tablets | 2 | 5 | .. | 481.28 | Viramune XR BY |

### RILPIVIRINE

**Authority required**

HIV infection

**Clinical criteria:**

Patient must be antiretroviral treatment naive,
Antivirals for treatment of HIV infections, combinations

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<tr>
<td>1170N</td>
<td>rilpivirine 25 mg tablet, 30</td>
<td>2</td>
<td>5</td>
<td>..</td>
<td>*571.64</td>
<td>Edurant JC</td>
</tr>
</tbody>
</table>

**Authority required**

HIV infection

Treatment Phase: Continuing

**Clinical criteria:**

- Patient must have previously received PBS-subsidised therapy for HIV infection,
- AND
- The treatment must be in combination with other antiretroviral agents.

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<tbody>
<tr>
<td>6458X</td>
<td>abacavir 600 mg + lamivudine 300 mg tablet, 30</td>
<td>2</td>
<td>5</td>
<td>..</td>
<td>*1008.44</td>
<td>Kivexa VI</td>
</tr>
</tbody>
</table>

**Authority required**

HIV infection

Treatment Phase: Initial

**Clinical criteria:**

- Patient must be antiretroviral treatment naive,
- AND
- The treatment must be in combination with other antiretroviral agents.

**Population criteria:**

- Patient must be aged 12 years or older,
- AND
- Patient must weigh 40 kg or more.

**Authority required**

HIV infection

Treatment Phase: Continuing

**Clinical criteria:**

- Patient must have previously received PBS-subsidised therapy for HIV infection,
- AND
- The treatment must be in combination with other antiretroviral agents.

**Population criteria:**

- Patient must be aged 12 years or older,
- AND
- Patient must weigh 40 kg or more.
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<tbody>
<tr>
<td>6327B</td>
<td>Patient must be aged 12 years or older, AND Patient must weigh 40 kg or more. <strong>abacavir 300 mg + lamivudine 150 mg + zidovudine 300 mg tablet, 60</strong></td>
<td>2</td>
<td>5</td>
<td>..</td>
<td>*1587.54</td>
<td>Trizivir VI</td>
</tr>
<tr>
<td>1490K</td>
<td><strong>EMTRICITABINE + RILPIVIRINE + TENOFOVIR</strong> Authority required HIV infection Treatment Phase: Initial Clinical criteria: Patient must be antiretroviral treatment naive. <strong>emtricitabine 200 mg + rilpivirine 25 mg + tenofovir disoproxil fumarate 300 mg tablet, 30</strong></td>
<td>2</td>
<td>5</td>
<td>..</td>
<td>*2120.12</td>
<td>Eviplera GI</td>
</tr>
<tr>
<td>6234D</td>
<td><strong>LAMIVUDINE + ZIDOVUDINE</strong> Authority required HIV infection Treatment Phase: Initial Clinical criteria: Patient must be antiretroviral treatment naive, AND The treatment must be in combination with other antiretroviral agents. <strong>lamivudine 150 mg + zidovudine 300 mg tablet, 60</strong></td>
<td>2</td>
<td>5</td>
<td>..</td>
<td>*1013.84</td>
<td>a Combivir VI Lamivudine 150 mg + Zidovudine 300 mg Alphapharm</td>
</tr>
<tr>
<td></td>
<td><strong>LOPINAVIR + RITONAVIR</strong> Authority required HIV infection Treatment Phase: Initial Clinical criteria: Patient must be antiretroviral treatment naive, AND The treatment must be in combination with other antiretroviral agents.</td>
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<tr>
<td>9633B</td>
<td>lopinavir 100 mg + ritonavir 25 mg tablet, 60</td>
<td>2</td>
<td>5</td>
<td>..</td>
<td>*362.96</td>
<td>Kaletra VE</td>
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<td>6495W</td>
<td>lopinavir 200 mg + ritonavir 50 mg tablet, 120</td>
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<td>5</td>
<td>..</td>
<td>*1416.76</td>
<td>Kaletra VE</td>
</tr>
<tr>
<td>6341R</td>
<td>lopinavir 400 mg/5 mL + ritonavir 100 mg/5 mL oral liquid, 60 mL</td>
<td>10</td>
<td>5</td>
<td>..</td>
<td>*1336.76</td>
<td>Kaletra VE</td>
</tr>
</tbody>
</table>

#### TENOFOVIR + EMTRICITABINE

**Authority required**
- HIV infection
- Treatment Phase: Initial
- Clinical criteria:
  - Patient must be antiretroviral treatment naive,
  - AND
  - The treatment must be in combination with other antiretroviral agents.

**Authority required**
- HIV infection
- Treatment Phase: Continuing
- Clinical criteria:
  - Patient must have previously received PBS-subsidised therapy for HIV infection,
  - AND
  - The treatment must be in combination with other antiretroviral agents.

<table>
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<th>Code</th>
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</thead>
<tbody>
<tr>
<td>6468K</td>
<td>tenofovir disoproxil fumarate 300 mg + emtricitabine 200 mg tablet, 30</td>
<td>2</td>
<td>5</td>
<td>..</td>
<td>*1576.96</td>
<td>Truvada GI</td>
</tr>
</tbody>
</table>

#### TENOFOVIR + EMTRICITABINE + EFAVIRENZ

**Authority required**
- HIV infection
- Treatment Phase: Initial
- Clinical criteria:
  - Patient must be antiretroviral treatment naive.

**Authority required**
- HIV infection
- Treatment Phase: Continuing
- Clinical criteria:
  - Patient must have previously received PBS-subsidised therapy for HIV infection.

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<tr>
<td>9650X</td>
<td>tenofovir disoproxil fumarate 300 mg + emtricitabine + efavirenz 600 mg tablet, 30</td>
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<td>..</td>
<td>*2120.12</td>
<td>Atripla GI</td>
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</table>

#### TENOFOVIR + EMTRICITABINE + ELVITEGRAVIR + COBICISTAT

**Authority required**
- HIV infection
- Treatment Phase: Initial
- Clinical criteria:
  - Patient must be antiretroviral treatment naive.

**Authority required**
- HIV infection
- Treatment Phase: Continuing
- Clinical criteria:
  - Patient must have previously received PBS-subsidised therapy for HIV infection.

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<tr>
<td>10085T</td>
<td>tenofovir disoproxil fumarate 300 mg + emtricitabine + elvitegravir + cobicistat</td>
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<td>5</td>
<td>..</td>
<td>*2120.12</td>
<td>Strivil GI</td>
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</table>

#### Other antivirals

**DOLUTEGRAVIR**

**Authority required**
### HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

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<td>HIV infection</td>
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<tr>
<td>Treatment Phase: Initial</td>
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<tr>
<td>Clinical criteria:</td>
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<tr>
<td>Patient must be antiretroviral treatment naive, AND The treatment must be in combination with other antiretroviral agents.</td>
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<tr>
<td>Authority required</td>
<td>HIV infection</td>
<td>Treatment Phase: Continuing</td>
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</tr>
<tr>
<td>Clinical criteria:</td>
<td>Patient must have previously received PBS-subsidised therapy for HIV infection, AND The treatment must be in combination with other antiretroviral agents.</td>
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<tr>
<td>10070B</td>
<td>dolutegravir 50 mg tablet, 30</td>
<td>2</td>
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<tr>
<td><strong>ENFUVIRID</strong></td>
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<td>HIV infection</td>
<td>Treatment Phase: Continuing</td>
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<tr>
<td>Clinical criteria:</td>
<td>Virological failure is defined as a viral load greater than 400 copies per mL on two consecutive occasions, while clinical failure is linked to emerging signs and symptoms of progressing HIV infection or treatment-limiting toxicity</td>
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<tr>
<td>6455R</td>
<td>enfuvirtide 90 mg injection [60 x 90 mg vials] (&amp;) inert substance diluent [60 x 1.1 mL vials], 1 pack</td>
<td>2</td>
<td>5</td>
<td>..</td>
<td>*4472.76</td>
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<tr>
<td><strong>MARAVIROC</strong></td>
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<td>Authority required</td>
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<td>Treatment Phase: Continuing</td>
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<tr>
<td>Clinical criteria:</td>
<td>Virological failure is defined as a viral load greater than 400 copies per mL on two consecutive occasions, while clinical failure is linked to emerging signs and symptoms of progressing HIV infection or treatment-limiting toxicity</td>
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<td>9572T</td>
<td>maraviroc 150 mg tablet, 60</td>
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<td>9573W</td>
<td>maraviroc 300 mg tablet, 60</td>
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<td>*1882.16</td>
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<tr>
<td><strong>RALTEGRAVIR</strong></td>
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<td>Authority required</td>
<td>HIV infection</td>
<td>Treatment Phase: Initial</td>
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<tr>
<td>Clinical criteria:</td>
<td>The treatment must be in combination with other antiretroviral agents, AND Patient must be antiretroviral experienced with at least 6 months therapy with 2 alternate classes of anti-retroviral therapy, AND Patient must have a CD4 count of less than 500 per cubic millimetre; OR Patient must have symptomatic HIV disease. Population criteria: Patient must be aged 2 years or older. Authority required</td>
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<td>694</td>
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<td>AND</td>
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<tr>
<td>AND</td>
<td>Patient must be antiretroviral experienced with at least 6 months therapy with 2 alternate classes of anti-retroviral therapy.</td>
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<td>AND</td>
<td>Patient must have previously received PBS-subsidised therapy for HIV infection.</td>
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<tr>
<td>Population criteria:</td>
<td>Patient must be aged 2 years or older.</td>
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<td>2754Y</td>
<td>raltegravir 100 mg tablet: chewable, 60</td>
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<td>5</td>
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<td>2743J</td>
<td>raltegravir 25 mg tablet: chewable, 60</td>
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<td>5</td>
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<td>$533.32</td>
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<tr>
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<td>Treatment Phase: Initial</td>
<td>Clinical criteria:</td>
<td>Patient must be antiretroviral treatment naive,</td>
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</table>
## ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

### ANTINEOPLASTIC AGENTS

#### ANTIMETABOLITES

**Pyrimidine analogues**

**AZACITIDINE**

**Authority required**

Initial PBS-subsidised treatment of a patient with:

1. Myelodysplastic syndrome classified as Intermediate-2 or high risk according to the International Prognostic Scoring System (IPSS); OR
2. Chronic Myelomonocytic Leukaemia (10% to 29% marrow blasts without Myeloproliferative Disorder); OR
3. Acute Myeloid Leukaemia with 20 to 30% marrow blasts and multi-lineage dysplasia, according to World Health Organisation (WHO) Classification.

Classification of a patient as Intermediate-2 requires a score of 1.5 to 2.0 on the IPSS, achieved with the possible combinations:

1. 11% to 30% marrow blasts with good karyotypic status (normal, -Y alone, del(5q) alone, del(20q) alone), and 0 to 1 cytopenias; OR
2. 11% to 20% marrow blasts with intermediate karyotypic status (other abnormalities), and 0 to 1 cytopenias; OR
3. 11% to 20% marrow blasts with good karyotypic status (normal, -Y alone, del(5q) alone, del(20q) alone), and 2 to 3 cytopenias; OR
4. 5% to 10% marrow blasts with poor karyotypic status (3 or more abnormalities or chromosome 7 anomalies), regardless of cytopenias; OR
5. 5% to 10% marrow blasts with intermediate karyotypic status (other abnormalities), and 2 to 3 cytopenias; OR
6. less than 5% marrow blasts with poor karyotypic status (3 or more abnormalities or chromosome 7 anomalies), and 2 to 3 cytopenias.

Classification of a patient as high risk requires a score of 2.5 or more on the IPSS, achieved with the possible combinations:

1. 21% to 30% marrow blasts with good karyotypic status (normal, -Y alone, del(5q) alone, del(20q) alone), and 2 to 3 cytopenias; OR
2. 21% to 30% marrow blasts with intermediate (other abnormalities) or poor karyotypic status (3 or more abnormalities or chromosome 7 anomalies), regardless of cytopenias; OR
3. 11% to 20% marrow blasts with poor karyotypic status (3 or more abnormalities or chromosome 7 anomalies), regardless of cytopenias; OR
4. 11% to 20% marrow blasts with intermediate karyotypic status (other abnormalities), and 2 to 3 cytopenias.

The first authority application must be made in writing and must include:

1. a completed authority prescription form; and
2. a completed Azacitidine PBS Authority Application - Supporting Information Form; and
3. a copy of the bone marrow biopsy report demonstrating that the patient has myelodysplastic syndrome, chronic myelomonocytic leukaemia or acute myeloid leukaemia; and
4. a copy of the full blood examination report; and
5. for myelodysplastic syndrome, a copy of the pathology report detailing the cytogenetics demonstrating intermediate-2 or high risk disease according to the International Prognostic Scoring System (IPSS); and
6. a signed patient acknowledgment form.

No more than three cycles will be authorised.

**Note**

Any queries concerning the arrangements to prescribe azacitidine may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe azacitidine should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

**Note**

Special Pricing Arrangements apply.

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<tr>
<td>6100C</td>
<td>azacitidine 100 mg injection, 1 x 100 mg vial</td>
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<td>2</td>
<td>..</td>
<td>*7746.80 Vidaza CJ</td>
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### HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

<table>
<thead>
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</thead>
<tbody>
<tr>
<td>(1)</td>
<td>Myelodysplastic syndrome classified as Intermediate-2 or high risk according to the International Prognostic Scoring System (IPSS); OR</td>
<td></td>
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<tr>
<td>(2)</td>
<td>Chronic Myelomonocytic Leukaemia (10% to 29% marrow blasts without Myeloproliferative Disorder); OR</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(3)</td>
<td>Acute Myeloid Leukaemia with 20 to 30% blasts and multi-lineage dysplasia, according to World Health Organisation (WHO) Classification; who has previously been issued with an authority prescription for azacitidine and does not have progressive disease. Authority applications for continuing treatment may be made by telephone on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Up to six cycles will be authorised</td>
<td></td>
<td></td>
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</tbody>
</table>

**Note**

Any queries concerning the arrangements to prescribe azacitidine may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe azacitidine should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

**Note**

Special Pricing Arrangements apply.

6138C azacitidine 100 mg injection, 1 x 100 mg vial 14 5 .. *7746.80 Vidaza CJ

### CYTOTOXIC ANTIBIOTICS AND RELATED SUBSTANCES

#### Anthracyclines and related substances

**DOXORUBICIN HYDROCHLORIDE-PEGYLATED LIPOSOMAL**

**Authority required**

Treatment of AIDS-related Kaposi's sarcoma in patients with CD4 cell counts of less than 200 per cubic millimetre and extensive mucocutaneous involvement

**Authority required**

Treatment of AIDS-related Kaposi's sarcoma in patients with CD4 cell counts of less than 200 per cubic millimetre and extensive visceral involvement

<table>
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<tr>
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<td>6249X</td>
<td>doxorubicin hydrochloride-pegylated liposomal 20 mg/10 mL injection, 1 x 10 mL vial</td>
<td>4</td>
<td>5</td>
<td>..</td>
<td></td>
<td>*2140.00</td>
<td>Caelyx JC</td>
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</tbody>
</table>

**Note**

Special Pricing Arrangements apply.

### IMMUNOSTIMULANTS

#### Colony stimulating factors

**FILGRASTIM**

**Authority required**

For use in a patient undergoing induction and consolidation therapy for acute myeloid leukaemia

**Authority required**

Mobilisation of peripheral blood progenitor cells to facilitate harvest of such cells for autologous transplantation into a patient with a non-myeloid malignancy who has had myeloablative or myelosuppressive therapy

**Authority required**

A patient receiving chemotherapy for myeloma who has had a prior episode of febrile neutropenia, and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned

**Authority required**

A patient with severe congenital neutropenia (absolute neutrophil count of less than 100 million cells per litre measured on 3 occasions, with readings at least 2 weeks apart, and in whom a bone marrow examination has shown evidence of maturational arrest of the neutrophil lineage)

**Authority required**

A patient with severe chronic neutropenia (absolute neutrophil count of less than 1,000 million cells per litre measured on 3 occasions, with readings at least 2 weeks apart, or evidence of neutrophil dysfunction, and, either having experienced a life-threatening infectious episode requiring hospitalisation and treatment with intravenous antibiotics in the previous 12 months, or having recurrent clinically significant infections (a minimum of 3 in the previous 12 months))

**Authority required**

A patient with chronic cyclic neutropenia (absolute neutrophil count of less than 500 million cells per litre lasting for 3 days per cycle, measured over
Authority required
A patient with inoperable Stage III, IVa or IVb squamous cell carcinoma of the oral cavity, larynx, oropharynx or hypopharynx receiving neoadjuvant treatment with docetaxel in combination with cisplatin and fluorouracil who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned

Authority required
Mobilisation of peripheral blood progenitor cells, in a normal volunteer, for use in allogeneic transplantation

Authority required
A patient receiving first-line chemotherapy for Hodgkin disease who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned

Authority required
A patient receiving chemotherapy for B-cell chronic lymphocytic leukaemia with fludarabine and cyclophosphamide who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned

Authority required
A patient receiving first-line chemotherapy for Hodgkin disease who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned

Authority required
A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in acute lymphoblastic leukaemia

Authority required
A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in breast cancer (adjuvant chemotherapy with docetaxel in combination with an anthracycline and cyclophosphamide)

Authority required
A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in germ cell tumours

Authority required
A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in neuroblastoma

Authority required
A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in non-Hodgkin lymphoma (aggressive grades; or low grade receiving an anthracycline-containing regimen)

Authority required
A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in relapsed Hodgkin disease

Authority required
A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in sarcoma

Authority required
A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in Hodgkin disease (first-line chemotherapy with escalated BEACOPP)

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<th>Price for Max. Dispensed *</th>
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<td>5830W</td>
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<td>Nivestim HH</td>
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<tr>
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<td>filgrastim 300 microgram/0.5 mL injection, 10 x 0.5 mL syringes</td>
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<td>*2562.30</td>
<td>TevaGrastim AS</td>
</tr>
<tr>
<td>6291D</td>
<td>filgrastim 300 microgram/0.5 mL injection, 10 x 0.5 mL syringes</td>
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</tr>
<tr>
<td>9693E</td>
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<td>..</td>
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<tr>
<td>Code</td>
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<td>..</td>
<td>*2562.28</td>
<td>Zarzio SZ</td>
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<tr>
<td>6126K</td>
<td>filgrastim 300 microgram/mL injection, 10 x 1 mL vials</td>
<td>2</td>
<td>11</td>
<td>..</td>
<td>*2562.30</td>
<td>Neupogen AN</td>
</tr>
<tr>
<td>6292E</td>
<td>filgrastim 480 microgram/0.5 mL injection, 10 x 0.5 mL syringes</td>
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<td>..</td>
<td>*4079.34</td>
<td>Neupogen AN</td>
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<tr>
<td>9695G</td>
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<td>Nivestim HH</td>
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<td>*4079.32</td>
<td>Zarzio SZ</td>
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<td>1113N</td>
<td>filgrastim 480 microgram/0.8 mL injection, 10 x 0.8 mL syringes</td>
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<td>11</td>
<td>..</td>
<td>*4079.34</td>
<td>TevaGrastim AS</td>
</tr>
<tr>
<td>6127L</td>
<td>filgrastim 480 microgram/1.6 mL injection, 10 x 1.6 mL vials</td>
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<td>11</td>
<td>..</td>
<td>*4079.34</td>
<td>Neupogen AN</td>
</tr>
</tbody>
</table>

**LENOGRASTIM**

**Authority required**

Mobilisation of peripheral blood progenitor cells to facilitate harvest of such cells for reinfusion into patients with non-myeloid malignancies who have had myeloablative or myelosuppressive therapy

**Authority required**

Mobilisation of peripheral blood progenitor cells, in normal volunteers, for use in allogeneic transplantation to facilitate harvest of such cells in healthy donors

**Authority required**

Patients with non-myeloid malignancies receiving marrow-ablative chemotherapy and subsequent peripheral blood progenitor cell or bone marrow transplantation

**Authority required**

Patients with breast cancer receiving standard dose adjuvant chemotherapy who have had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned

**Authority required**

Patients receiving first-line chemotherapy for Hodgkin’s disease who have had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned

**Authority required**

Patients being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in relapsed Hodgkin’s disease

**Authority required**

Patients being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in rhabdomyosarcoma

**Authority required**

Patients being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in Ewing’s sarcoma

**Authority required**

Patients being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in germ cell tumours

**Authority required**

Patients being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in infants and children with CNS tumours

**Authority required**

Patients being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in neuroblastoma

**Authority required**

Patients being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in non-Hodgkin’s lymphoma (intermediate or high grade)

**Authority required**

Patients being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in osteosarcoma

**Authority required**

Patients being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in acute lymphoblastic leukaemia

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<td>6337M</td>
<td>LENOGRASTIM Powder for injection 13,400,000 i.u. (105 micrograms) vial, 10</td>
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<tr>
<td>6338N</td>
<td>LENOGRASTIM Powder for injection 33,600,000 i.u. (263 micrograms) vial, 10</td>
<td>2</td>
<td>11</td>
<td>..</td>
<td>*2613.96</td>
<td>Granocyte 34 HH</td>
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</table>

**PEGFILGRASTIM**
### Authority required

For use in a patient undergoing induction and consolidation therapy for acute myeloid leukaemia

### Authority required

A patient with breast cancer receiving standard dose adjuvant chemotherapy who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned

### Authority required

A patient receiving chemotherapy for B-cell chronic lymphocytic leukaemia with fludarabine and cyclophosphamide who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned

### Authority required

A patient receiving first-line chemotherapy for Hodgkin disease who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned

### Authority required

A patient receiving chemotherapy for myeloma who has had a prior episode of febrile neutropenia, and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned

### Authority required

A patient receiving chemotherapy for B-cell chronic lymphocytic leukaemia with fludarabine and cyclophosphamide who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned

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A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in breast cancer (adjuvant chemotherapy with docetaxel in combination with an anthracycline and cyclophosphamide)

### Authority required

A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in germ cell tumours

### Authority required

A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in infants and children with CNS tumours

### Authority required

A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in neuroblastoma

### Authority required

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A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in relapsed Hodgkin disease

### Authority required

A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in sarcoma

### Authority required

A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in Hodgkin disease (first-line chemotherapy with escalated BEACOPP)

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<tbody>
<tr>
<td>6363X</td>
<td>pegfilgrastim 6 mg/0.6 mL injection, 1 x 0.6 mL syringe</td>
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<td>11</td>
<td>..</td>
<td>1971.76</td>
<td>Neulasta AN</td>
</tr>
</tbody>
</table>

### Interferons

#### INTERFERON ALFA-2A

### Authority required

Use in the treatment of Philadelphia chromosome positive myelogenous leukaemia in the chronic phase

### Authority required

Chronic hepatitis B in a patient without cirrhosis who satisfies all of the following criteria:

1. Elevated HBV DNA levels - greater than 20,000 IU/mL (100,000 copies/mL) if HBeAg positive, or greater than 2,000 IU/mL (10,000 copies/mL) if HBeAg negative - in conjunction with documented chronic hepatitis B infection;
(2) Evidence of chronic liver injury as determined by:
(a) Confirmed elevated serum ALT; or
(b) Liver biopsy

**Authority required**
Chronic hepatitis B in a patient with cirrhosis who has detectable HBV DNA.

Persons with Child’s class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy

**Caution**
Treatment with interferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored.

6210W interferon alfa-2a 3 million international units/0.5 mL injection, 1 x 0.5 mL syringe 30 5 .. *936.46 Roferon-A RO

6211X interferon alfa-2a 4.5 million international units/0.5 mL injection, 1 x 0.5 mL syringe 30 5 .. *1387.66 Roferon-A RO

6212Y interferon alfa-2a 6 million international units/0.5 mL injection, 1 x 0.5 mL syringe 30 5 .. *1834.06 Roferon-A RO

6213B interferon alfa-2a 9 million international units/0.5 mL injection, 1 x 0.5 mL syringe 30 5 .. *2728.06 Roferon-A RO

**INTERFERON ALFA-2B**

**Authority required**
Adjunctive therapy of malignant melanoma following surgery in patients with nodal involvement

**Authority required**
Use in the treatment of Philadelphia chromosome positive myelogenous leukaemia in the chronic phase

**Authority required**
Chronic hepatitis B in a patient without cirrhosis who satisfies all of the following criteria:
(1) Elevated HBV DNA levels - greater than 20,000 IU/mL (100,000 copies/mL) if HBeAg positive, or greater than 2,000 IU/mL (10,000 copies/mL) if HBeAg negative - in conjunction with documented chronic hepatitis B infection;
(2) Evidence of chronic liver injury as determined by:
(a) Confirmed elevated serum ALT; or
(b) Liver biopsy

**Authority required**
Chronic hepatitis B in a patient with cirrhosis who has detectable HBV DNA.

Persons with Child’s class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy

**Caution**
Treatment with interferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored.

6246R interferon alfa-2b 10 million international units/mL injection, 5 x 1 mL vials 3 5 .. *1536.25 Intron A MK

6253D interferon alfa-2b 18 million international units/1.2 mL injection, 1 x 1.2 mL cartridge 2 5 .. *378.54 Intron A Redipen MK

6218G interferon alfa-2b 18 million international units/3 mL injection, 1 x 3 mL vial 15 5 .. *2727.91 Intron A MK

6219H interferon alfa-2b 25 million international units/2.5 mL injection, 1 x 2.5 mL vial 15 5 .. *3770.56 Intron A MK

6254E interferon alfa-2b 30 million international units/1.2 mL injection, 1 x 1.2 mL cartridge 2 5 .. *626.40 Intron A Redipen MK

6255F interferon alfa-2b 60 million international units/1.2 mL injection, 1 x 1.2 mL cartridge 2 5 .. *1238.36 Intron A Redipen MK

**INTERFERON GAMMA-1B**

**Authority required**
Treatment of chronic granulomatous disease in patients with frequent and severe infections despite adequate prophylaxis with antimicrobial agents

6148N interferon gamma-1b 2 million international units (100 microgram/0.5 mL) injection, 6 x 0.5 mL vials 2 11 .. *2768.56 Imukin BY

**PEGINTERFERON ALFA-2A**

**Authority required**
Treatment, as sole PBS-subsidised therapy, in a patient with chronic hepatitis B without cirrhosis who satisfies all of the following criteria:
### HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

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<td>Pegasys RO</td>
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<td>6449K</td>
<td>peginterferon alfa-2a 180 microgram/0.5 mL injection, 4 x 0.5 mL syringes</td>
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<td>5</td>
<td>..</td>
<td>*2747.22</td>
<td>Pegasys RO</td>
</tr>
</tbody>
</table>

**PEGINTERFERON ALFA-2A (&) RIBAVIRIN**

**Authority required**

Chronic genotype 1 hepatitis C infection

**Clinical criteria:**

Patient must have compensated liver disease,

AND

Patient must have failed prior treatment with interferon based therapies (non-pegylated or pegylated),

AND

Patient must have received no more than one prior treatment with interferon alfa or peginterferon alfa for hepatitis C if using peginterferon and ribavirin without an NS3 protease inhibitor, or, in triple combination therapy with boceprevir; OR

Patient must have received prior treatment with interferon alfa or peginterferon alfa for hepatitis C if using peginterferon and ribavirin in triple combination therapy with telaprevir,

AND

The treatment must be limited to a maximum duration of 24 weeks in patients using peginterferon and ribavirin in triple combination therapy with telaprevir who were prior treatment relapsers and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at weeks 4 and 12; OR

The treatment must be limited to a maximum duration of 36 weeks in patients using peginterferon and ribavirin in triple combination therapy with boceprevir who were prior treatment partial responders or relapers and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at weeks 8 and 12; OR

The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin without an NS3 protease inhibitor; OR

The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin in triple combination therapy with boceprevir who: (i) were prior treatment null responders; or (ii) were prior treatment partial responders or relapers and in whom plasma HCV RNA...
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</table>

is detectable by an HCV RNA qualitative assay at week 8, and undetectable by an HCV RNA qualitative assay at week 12; or (iii) have hepatic cirrhosis; OR

The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin in triple combination therapy with telaprevir who: (i) were prior treatment partial or null responders; or (ii) were prior treatment relapers and for whom the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is detectable but less than or equal to 1000 IU/mL; or (iii) have hepatic cirrhosis.

AND

The treatment must cease in patients using peginterferon and ribavirin without an NS3 protease inhibitor if HCV RNA is detectable by an HCV RNA qualitative assay at week 12.

AND

The treatment must cease in patients using peginterferon and ribavirin in combination with boceprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12.

AND

The treatment must cease in patients using peginterferon and ribavirin in combination with boceprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24.

AND

The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is greater than 1000 IU/mL.

AND

The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12.

AND

The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24.

Population criteria:

Patient must be aged 18 years or older.

AND

Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

Treatment criteria:

Must be treated in an accredited treatment centre.

Evidence of chronic genotype 1 hepatitis C infection (repeatedly anti-HCV positive and HCV RNA positive) must be documented in the patient’s medical records.

Note

No increase in the maximum quantity or number of units may be authorised.

Note

No increase in the maximum number of repeats may be authorised.

Note

Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:

(a) a nurse educator/counsellor for patients; and

(b) 24-hour access by patients to medical advice; and

(c) an established liver clinic.

Authority required

Chronic genotype 1 hepatitis C infection

Clinical criteria:

Patient must have compensated liver disease.

AND

Patient must not have received prior interferon alfa or peginterferon alfa treatment for hepatitis C.

AND

The treatment must be limited to a maximum duration of 24 weeks in patients using peginterferon and ribavirin in triple combination therapy with telaprevir and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at weeks 4 and 12; OR

The treatment must be limited to a maximum duration of 28 weeks in patients using peginterferon and ribavirin in triple combination therapy with boceprevir and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at weeks 8 and 24; OR

The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin without an NS3 protease inhibitor; OR

The treatment must be limited to a maximum duration of 48 weeks in patients: (i) using peginterferon and ribavirin in triple combination therapy
with boceprevir and in whom plasma HCV RNA is detectable by an HCV RNA qualitative assay at week 24; or (ii) using peginterferon and ribavirin in triple combination therapy with boceprevir who have hepatic cirrhosis; OR

The treatment must be limited to a maximum duration of 48 weeks in patients: (i) using peginterferon and ribavirin in triple combination therapy with telaprevir and for whom the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is detectable but less than or equal to 1000 IU/mL; or (ii) using peginterferon and ribavirin in triple combination therapy with telaprevir who have hepatic cirrhosis.

AND

The treatment must cease in patients using peginterferon and ribavirin without an NS3 protease inhibitor unless the results of an HCV RNA quantitative assay at week 12 (performed at the same laboratory using the same test) show that plasma HCV RNA has become undetectable or the viral load has decreased by at least a 2 log drop,

AND

The treatment must cease in patients using peginterferon and ribavirin in combination with boceprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24,

AND

The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is greater than 1000 IU/mL,

AND

The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12,

AND

The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24.

Population criteria:

Patient must be aged 18 years or older,

AND

Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

Treatment criteria:

Must be treated in an accredited treatment centre.

Evidence of chronic hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient’s medical records.

For patients using peginterferon and ribavirin without an NS3 protease inhibitor who are viral negative at week 12, an HCV RNA qualitative assay at week 24 is unnecessary.

Note

No increase in the maximum quantity or number of units may be authorised.

Note

No increase in the maximum number of repeats may be authorised.

Note

Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:

(a) a nurse educator/counsellor for patients; and

(b) 24-hour access by patients to medical advice; and

(c) an established liver clinic.

Authority required

Chronic non-genotype 1 hepatitis C infection

Clinical criteria:

The treatment must be the sole PBS-subsidised treatment for hepatitis C,

AND

Patient must have compensated liver disease,

AND

The condition must be genotype 2, 3, 4, 5 or 6 hepatitis C,

AND

Patient must have failed prior treatment with interferon based therapies (non-pegylated or pegylated),

AND

Patient must have received no more than one prior treatment with interferon alfa or peginterferon alfa for hepatitis C,

AND

The treatment must be limited to a maximum duration of 48 weeks,
### HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

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**AND**

The treatment must cease if HCV RNA is detectable by an HCV RNA qualitative assay at week 12.

**Population criteria:**

Patient must be aged 18 years or older,

**AND**

Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

**Treatment criteria:**

Must be treated in an accredited treatment centre.

Evidence of chronic hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.

**Note**

No increase in the maximum quantity or number of units may be authorised.

**Note**

No increase in the maximum number of repeats may be authorised.

**Note**

Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:

(a) a nurse educator/counsellor for patients; and
(b) 24-hour access by patients to medical advice; and
(c) an established liver clinic.

**Authority required**

Chronic non-genotype 1 hepatitis C infection

**Clinical criteria:**

The treatment must be the sole PBS-subsidised treatment for hepatitis C,

**AND**

Patient must have compensated liver disease,

**AND**

Patient must not have received prior interferon alfa or peginterferon alfa treatment for hepatitis C,

**AND**

The condition must be genotype 2, 3, 4, 5 or 6 hepatitis C,

**AND**

The treatment must be limited to a maximum duration of 24 weeks for patients with genotype 2 or 3 hepatitis C without hepatic cirrhosis or bridging fibrosis; OR

The treatment must be limited to a maximum duration of 48 weeks for patients with genotype 4, 5 or 6 hepatitis C; OR

The treatment must be limited to a maximum duration of 48 weeks for patients with genotype 2 or 3 hepatitis C with hepatic cirrhosis or bridging fibrosis,

**AND**

The treatment must cease in patients with genotype 4, 5, or 6 hepatitis C unless the results of an HCV RNA quantitative assay at week 12 (performed at the same laboratory using the same test) shows that plasma HCV RNA has become undetectable or the viral load has decreased by at least a 2 log drop.

**AND**

The treatment must cease in patients eligible for 48 weeks of treatment if HCV RNA is detectable by an HCV RNA qualitative assay at week 24.

**Population criteria:**

Patient must be aged 18 years or older,

**AND**

Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

**Treatment criteria:**

Must be treated in an accredited treatment centre.

Evidence of chronic hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.

For patients with genotype 4, 5, or 6 who are viral negative at week 12, an HCV RNA qualitative assay at week 24 is unnecessary.

For patients with genotype 2 or 3 without cirrhosis, an HCV RNA assay at week 12 is unnecessary because of the high likelihood of early viral response by week 12.

For patients who are eligible for 24 weeks of treatment, a maximum of 2 repeats may be prescribed.
For patients who are eligible for 48 weeks of treatment, a maximum of 5 repeats may be prescribed.

**Caution**
Treatment with peginterferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored.

**Caution**
Ribavirin is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and during the 6 months period after cessation of treatment.

**Note**
Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:
(a) a nurse educator/counsellor for patients; and
(b) 24-hour access by patients to medical advice; and
(c) an established liver clinic.

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**PEGINTERFERON ALFA-2B (&) RIBAVIRIN**

**Authority required**
Chronic genotype 1 hepatitis C infection

**Clinical criteria:**
The treatment must be the sole PBS-subsidised treatment for hepatitis C,

AND
Patient must have compensated liver disease,

AND
Patient must have failed prior treatment with interferon based therapies (non-pegylated or pegylated),

AND
Patient must have received no more than one prior treatment with interferon alfa or peginterferon alfa for hepatitis C,

AND
The treatment must be limited to a maximum duration of 48 weeks,

AND
The treatment must cease if HCV RNA is detectable by an HCV RNA qualitative assay at week 12.

**Population criteria:**
Patient must weigh at least 27 kg.

AND
Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

**Treatment criteria:**
Must be treated in an accredited treatment centre.

Evidence of chronic genotype 1 hepatitis C infection (repeatedly anti-HCV positive and HCV RNA positive) must be documented in the patient’s medical records.

**Note**
No increase in the maximum quantity or number of units may be authorised.

**Note**
No increase in the maximum number of repeats may be authorised.

**Note**
Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:
(a) a nurse educator/counsellor for patients; and
**HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)**

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(b) 24-hour access by patients to medical advice; and
(c) an established liver clinic.

**Authority required**

Chronic genotype 1 hepatitis C infection

**Clinical criteria:**

The treatment must be the sole PBS-subsidised treatment for hepatitis C,

**AND**

Patient must have compensated liver disease,

**AND**

Patient must not have received prior interferon alfa or peginterferon alfa treatment for hepatitis C,

**AND**

The treatment must be limited to a maximum duration of 48 weeks,

**AND**

The treatment must cease unless the results of an HCV RNA quantitative assay at week 12 (performed at the same laboratory using the same test) show that plasma HCV RNA has become undetectable or the viral load has decreased by at least a 2 log drop.

**Population criteria:**

Patient must weigh at least 27 kg,

**AND**

Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

**Treatment criteria:**

Must be treated in an accredited treatment centre.

Evidence of chronic hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient’s medical records.

For patients who are viral negative at week 12, an HCV RNA qualitative assay at week 24 is unnecessary.

**Note**

No increase in the maximum quantity or number of units may be authorised.

**Note**

No increase in the maximum number of repeats may be authorised.

**Note**

Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:

(a) a nurse educator/counsellor for patients; and
(b) 24-hour access by patients to medical advice; and
(c) an established liver clinic.

**Authority required**

Chronic non-genotype 1 hepatitis C infection

**Clinical criteria:**

The treatment must be the sole PBS-subsidised treatment for hepatitis C,

**AND**

Patient must have compensated liver disease,

**AND**

The condition must be genotype 2, 3, 4, 5 or 6 hepatitis C,

**AND**

Patient must have failed prior treatment with interferon based therapies (non-pegylated or pegylated),

**AND**

Patient must have received no more than one prior treatment with interferon alfa or peginterferon alfa for hepatitis C,

**AND**

The treatment must be limited to a maximum duration of 48 weeks,

**AND**

The treatment must cease if HCV RNA is detectable by an HCV RNA qualitative assay at week 12.

**Population criteria:**

Patient must weigh at least 27 kg.
Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

**Treatment criteria:**
Must be treated in an accredited treatment centre.

Evidence of chronic hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient’s medical records.

**Note**
No increase in the maximum quantity or number of units may be authorised.

**Note**
No increase in the maximum number of repeats may be authorised.

**Note**
Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:
(a) a nurse educator/counsellor for patients; and
(b) 24-hour access by patients to medical advice; and
(c) an established liver clinic.

**Authority required**
Chronic non-genotype 1 hepatitis C infection

**Clinical criteria:**
The treatment must be the sole PBS-subsidised treatment for hepatitis C,

AND
Patient must have compensated liver disease,

AND
Patient must not have received prior interferon alfa or peginterferon alfa treatment for hepatitis C,

AND
The condition must be genotype 2, 3, 4, 5 or 6 hepatitis C,

AND
The treatment must be limited to a maximum duration of 24 weeks for patients with genotype 2 or 3 hepatitis C without hepatic cirrhosis or bridging fibrosis; OR
The treatment must be limited to a maximum duration of 48 weeks for patients with genotype 4, 5 or 6 hepatitis C; OR
The treatment must be limited to a maximum duration of 48 weeks for patients with genotype 2 or 3 hepatitis C with hepatic cirrhosis or bridging fibrosis,

AND
The treatment must cease in patients with genotype 4, 5, or 6 hepatitis C unless the results of an HCV RNA quantitative assay at week 12 (performed at the same laboratory using the same test) shows that plasma HCV RNA has become undetectable or the viral load has decreased by at least a 2 log drop,

AND
The treatment must cease in patients eligible for 48 weeks of treatment if HCV RNA is detectable by an HCV RNA qualitative assay at week 24.

**Population criteria:**
Patient must weigh at least 27 kg,

AND
Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

**Treatment criteria:**
Must be treated in an accredited treatment centre.

Evidence of chronic hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient’s medical records.

For patients with genotype 4, 5, or 6 who are viral negative at week 12, an HCV RNA qualitative assay at week 24 is unnecessary.

For patients with genotype 2 or 3 without cirrhosis, an HCV RNA assay at week 12 is unnecessary because of the high likelihood of early viral response by week 12.

For patients who are eligible for 24 weeks of treatment, a maximum of 2 repeats may be prescribed.

For patients who are eligible for 48 weeks of treatment, a maximum of 5 repeats may be prescribed.

**Note**
Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:
(a) a nurse educator/counsellor for patients; and
(b) 24-hour access by patients to medical advice; and
(c) an established liver clinic.

**Authority required**
Chronic genotype 1 hepatitis C infection

**Clinical criteria:**

AND

Patient must have compensated liver disease,

AND

Patient must have received prior treatment with interferon based therapies (non-pegylated or pegylated),

AND

Patient must have received prior treatment with interferon alfa or peginterferon alfa for hepatitis C if using peginterferon and ribavirin without an NS3 protease inhibitor, or, in triple combination therapy with boceprevir; OR

Patient must have received prior treatment with interferon alfa or peginterferon alfa for hepatitis C if using peginterferon and ribavirin in triple combination therapy with telaprevir,

AND

The treatment must be limited to a maximum duration of 24 weeks in patients using peginterferon and ribavirin in triple combination therapy with telaprevir who were prior treatment relapers and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at weeks 4 and 12; OR

The treatment must be limited to a maximum duration of 36 weeks in patients using peginterferon and ribavirin in triple combination therapy with boceprevir who were prior treatment partial responders or relapers and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at weeks 8 and 12; OR

The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin without an NS3 protease inhibitor; OR

The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin in triple combination therapy with boceprevir who: (i) were prior treatment null responders; or (ii) were prior treatment partial responders or relapers and in whom plasma HCV RNA is detectable by an HCV RNA qualitative assay at week 8, and undetectable by an HCV RNA qualitative assay at week 12; or (iii) have hepatic cirrhosis; OR

The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin in triple combination therapy with telaprevir who: (i) were prior treatment partial or null responders; or (ii) were prior treatment relapers and for whom the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is detectable but less than or equal to 1000 IU/mL; or (iii) have hepatic cirrhosis,

AND

The treatment must cease in patients using peginterferon and ribavirin without an NS3 protease inhibitor if HCV RNA is detectable by an HCV RNA qualitative assay at week 12,

AND

The treatment must cease in patients using peginterferon and ribavirin in combination with boceprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12,

AND

The treatment must cease in patients using peginterferon and ribavirin in combination with boceprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24,

AND

The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is greater than 1000 IU/mL,

AND

The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12,

AND

The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24.

**Population criteria:**

Patient must be aged 18 years or older,

AND

Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

**Treatment criteria:**

Must be treated in an accredited treatment centre.

Evidence of chronic genotype 1 hepatitis C infection (repeatedly anti-HCV positive and HCV RNA positive) must be documented in the patient's
Note
No increase in the maximum quantity or number of units may be authorised.

Note
No increase in the maximum number of repeats may be authorised.

Note
Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:
(a) a nurse educator/counsellor for patients; and
(b) 24-hour access by patients to medical advice; and
(c) an established liver clinic.

Authority required
Chronic genotype 1 hepatitis C infection

Clinical criteria:
Patient must have compensated liver disease,
AND
Patient must not have received prior interferon alfa or peginterferon alfa treatment for hepatitis C,
AND
The treatment must be limited to a maximum duration of 24 weeks in patients using peginterferon and ribavirin in triple combination therapy with telaprevir and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at weeks 4 and 12; OR
The treatment must be limited to a maximum duration of 28 weeks in patients using peginterferon and ribavirin in triple combination therapy with boceprevir and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at weeks 8 and 24; OR
The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin without an NS3 protease inhibitor; OR
The treatment must be limited to a maximum duration of 48 weeks in patients: (i) using peginterferon and ribavirin in triple combination therapy with boceprevir and for whom the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is detectable but less than or equal to 1000 IU/mL; or (ii) using peginterferon and ribavirin in triple combination therapy with telaprevir who have hepatic cirrhosis;
AND
The treatment must cease in patients using peginterferon and ribavirin without an NS3 protease inhibitor unless the results of an HCV RNA quantitative assay at week 12 (performed at the same laboratory using the same test) show that plasma HCV RNA has become undetectable or the viral load has decreased by at least a 2 log drop,
AND
The treatment must cease in patients using peginterferon and ribavirin in combination with boceprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24,
AND
The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is greater than 1000 IU/mL,
AND
The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12,
AND
The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24.

Population criteria:
Patient must be aged 18 years or older,
AND
Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

Treatment criteria:
Must be treated in an accredited treatment centre.
Evidence of chronic hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient’s medical records.
For patients using peginterferon and ribavirin without an NS3 protease inhibitor who are viral negative at week 12, an HCV RNA qualitative assay at week 24 is unnecessary.
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**Note**
No increase in the maximum quantity or number of units may be authorised.

**Note**
No increase in the maximum number of repeats may be authorised.

**Note**
Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:
(a) a nurse educator/counsellor for patients; and
(b) 24-hour access by patients to medical advice; and
(c) an established liver clinic.

**Authority required**
Chronic non-genotype 1 hepatitis C infection

**Clinical criteria:**
The treatment must be the sole PBS-subsidised treatment for hepatitis C,
AND
Patient must have compensated liver disease,
AND
The condition must be genotype 2, 3, 4, 5 or 6 hepatitis C,
AND
Patient must have failed prior treatment with interferon based therapies (non-pegylated or pegylated),
AND
Patient must have received no more than one prior treatment with interferon alfa or peginterferon alfa for hepatitis C,
AND
The treatment must be limited to a maximum duration of 48 weeks,
AND
The treatment must cease if HCV RNA is detectable by an HCV RNA qualitative assay at week 12.

**Population criteria:**
Patient must be aged 18 years or older,
AND
Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

**Treatment criteria:**
Must be treated in an accredited treatment centre.
Evidence of chronic hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient’s medical records.

**Note**
No increase in the maximum quantity or number of units may be authorised.

**Note**
No increase in the maximum number of repeats may be authorised.

**Note**
Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:
(a) a nurse educator/counsellor for patients; and
(b) 24-hour access by patients to medical advice; and
(c) an established liver clinic.

**Authority required**
Chronic non-genotype 1 hepatitis C infection

**Clinical criteria:**
The treatment must be the sole PBS-subsidised treatment for hepatitis C,
AND
Patient must have compensated liver disease,
AND
Patient must not have received prior interferon alfa or peginterferon alfa treatment for hepatitis C,
The condition must be genotype 2, 3, 4, 5 or 6 hepatitis C,
AND
The treatment must be limited to a maximum duration of 24 weeks for patients with genotype 2 or 3 hepatitis C without hepatic cirrhosis or bridging fibrosis; OR
The treatment must be limited to a maximum duration of 48 weeks for patients with genotype 4, 5 or 6 hepatitis C; OR
The treatment must be limited to a maximum duration of 48 weeks for patients with genotype 2 or 3 hepatitis C with hepatic cirrhosis or bridging fibrosis,
AND
The treatment must cease in patients with genotype 4, 5, or 6 hepatitis C unless the results of an HCV RNA quantitative assay at week 12 (performed at the same laboratory using the same test) shows that plasma HCV RNA has become undetectable or the viral load has decreased by at least a 2 log drop,
AND
The treatment must cease in patients eligible for 48 weeks of treatment if HCV RNA is detectable by an HCV RNA qualitative assay at week 24.
Population criteria:
Patient must be aged 18 years or older,
AND
Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.
Treatment criteria:
Must be treated in an accredited treatment centre.
Evidence of chronic hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient’s medical records.
For patients with genotype 4, 5, or 6 who are viral negative at week 12, an HCV RNA qualitative assay at week 24 is unnecessary.
For patients with genotype 2 or 3 without cirrhosis, an HCV RNA assay at week 12 is unnecessary because of the high likelihood of early viral response by week 12.
For patients who are eligible for 24 weeks of treatment, a maximum of 2 repeats may be prescribed.
For patients who are eligible for 48 weeks of treatment, a maximum of 5 repeats may be prescribed.
Caution
Treatment with peginterferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored.
Caution
Ribavirin is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and during the 6 months period after cessation of treatment.
Note
Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:
(a) a nurse educator/counsellor for patients; and
(b) 24-hour access by patients to medical advice; and
(c) an established liver clinic.

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<td>6405D</td>
<td>peginterferon alfa-2b 100 microgram injection [4 x 100 microgram cartridges] (&amp;) ribavirin 200 mg capsule [112 capsules] (&amp;) inert substance diluent [4 x 0.5 mL cartridges], 1 pack</td>
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<td>5</td>
<td>..</td>
<td>*3146.38</td>
<td>Pegatron MK</td>
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<td>6400W</td>
<td>peginterferon alfa-2b 50 microgram injection [4 x 50 microgram cartridges] (&amp;) ribavirin 200 mg capsule [112 capsules] (&amp;) inert substance diluent [4 x 0.5 mL cartridges], 1 pack</td>
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<td>*2166.50</td>
<td>Pegatron MK</td>
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<td>6401X</td>
<td>peginterferon alfa-2b 80 microgram injection [4 x 80 microgram cartridges] (&amp;) ribavirin 200 mg capsule [84 capsules] (&amp;) inert substance diluent [4 x 0.5 mL cartridges], 1 pack</td>
<td>2</td>
<td>5</td>
<td>..</td>
<td>*2469.48</td>
<td>Pegatron MK</td>
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</tbody>
</table>

PEGINTERFERON ALFA-2B (&) RIBAVIRIN

Authority required
Chronic genotype 1 hepatitis C infection
Clinical criteria:
Patient must have compensated liver disease,
AND
Patient must have failed prior treatment with interferon based therapies (non-pegylated or pegylated),
AND

Patient must have received no more than one prior treatment with interferon alfa or peginterferon alfa for hepatitis C if using peginterferon and ribavirin without an NS3 protease inhibitor, or, in triple combination therapy with boceprevir; OR

Patient must have received prior treatment with interferon alfa or peginterferon alfa for hepatitis C if using peginterferon and ribavirin in triple combination therapy with telaprevir;

AND

The treatment must be limited to a maximum duration of 24 weeks in patients using peginterferon and ribavirin in triple combination therapy with telaprevir who were prior treatment relapers and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at weeks 4 and 12; OR

The treatment must be limited to a maximum duration of 36 weeks in patients using peginterferon and ribavirin in triple combination therapy with boceprevir who were prior treatment partial responders or relapers and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at weeks 8 and 12; OR

The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin without an NS3 protease inhibitor; OR

The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin in triple combination therapy with boceprevir who: (i) were prior treatment null responders; or (ii) were prior treatment partial responders or relapers and in whom plasma HCV RNA is detectable by an HCV RNA qualitative assay at week 8, and undetectable by an HCV RNA qualitative assay at week 12; or (iii) have hepatic cirrhosis; OR

The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin in triple combination therapy with telaprevir who: (i) were prior treatment partial or null responders; or (ii) were prior treatment relapers and for whom the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is detectable but less than or equal to 1000 IU/mL; or (iii) have hepatic cirrhosis,

AND

The treatment must cease in patients using peginterferon and ribavirin without an NS3 protease inhibitor if HCV RNA is detectable by an HCV RNA qualitative assay at week 12,

AND

The treatment must cease in patients using peginterferon and ribavirin in combination with boceprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12.

AND

The treatment must cease in patients using peginterferon and ribavirin in combination with boceprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24.

AND

The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is greater than 1000 IU/mL.

AND

The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12.

AND

The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24.

Population criteria:

Patient must be aged 18 years or older,

AND

Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

Treatment criteria:

Must be treated in an accredited treatment centre.

Evidence of chronic genotype 1 hepatitis C infection (repeatedly anti-HCV positive and HCV RNA positive) must be documented in the patient’s medical records.

Note

No increase in the maximum quantity or number of units may be authorised.

Note

No increase in the maximum number of repeats may be authorised.

Note

Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:

(a) a nurse educator/counsellor for patients; and

(b) 24-hour access by patients to medical advice; and
### Chronic genotype 1 hepatitis C infection

**Clinical criteria:**

- Patient must have compensated liver disease,
- Patient must not have received prior interferon alfa or peginterferon alfa treatment for hepatitis C,

**AND**

- The treatment must be limited to a maximum duration of 24 weeks in patients using peginterferon and ribavirin in triple combination therapy with telaprevir and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at weeks 4 and 12; OR
- The treatment must be limited to a maximum duration of 28 weeks in patients using peginterferon and ribavirin in triple combination therapy with boceprevir and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at weeks 8 and 24; OR
- The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin without an NS3 protease inhibitor; OR
- The treatment must be limited to a maximum duration of 48 weeks in patients: (i) using peginterferon and ribavirin in triple combination therapy with telaprevir and for whom the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is detectable but less than or equal to 1000 IU/mL; or (ii) using peginterferon and ribavirin in triple combination therapy with boceprevir who have hepatic cirrhosis,

**AND**

- The treatment must cease in patients using peginterferon and ribavirin without an NS3 protease inhibitor unless the results of an HCV RNA quantitative assay at week 12 (performed at the same laboratory using the same test) show that plasma HCV RNA has become undetectable or the viral load has decreased by at least a 2 log drop,
- The treatment must cease in patients using peginterferon and ribavirin in combination with boceprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24,

**AND**

- The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is greater than 1000 IU/mL,
- The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12,
- The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24.

**Population criteria:**

- Patient must be aged 18 years or older,
- Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

**Treatment criteria:**

- Must be treated in an accredited treatment centre.
- Evidence of chronic hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient’s medical records.
- For patients using peginterferon and ribavirin without an NS3 protease inhibitor who are viral negative at week 12, an HCV RNA qualitative assay at week 24 is unnecessary.

**Note**

- No increase in the maximum quantity or number of units may be authorised.

**Note**

- No increase in the maximum number of repeats may be authorised.

**Note**

- Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:
  - (a) a nurse educator/counsellor for patients; and
  - (b) 24-hour access by patients to medical advice; and
  - (c) an established liver clinic.
**Highly Specialised Drugs Program (Private Hospital)**

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>Dispensed Price for Max. Qty $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
</table>

**Authority required**

Chronic non-genotype 1 hepatitis C infection

**Clinical criteria:**

The treatment must be the sole PBS-subsidised treatment for hepatitis C,

AND

Patient must have compensated liver disease,

AND

The condition must be genotype 2, 3, 4, 5 or 6 hepatitis C,

AND

Patient must have failed prior treatment with interferon based therapies (non-pegylated or pegylated),

AND

Patient must have received no more than one prior treatment with interferon alfa or peginterferon alfa for hepatitis C,

AND

The treatment must be limited to a maximum duration of 48 weeks,

AND

The treatment must cease if HCV RNA is detectable by an HCV RNA qualitative assay at week 12.

**Population criteria:**

Patient must be aged 18 years or older,

AND

Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

**Treatment criteria:**

Must be treated in an accredited treatment centre.

Evidence of chronic hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.

**Note**

No increase in the maximum quantity or number of units may be authorised.

**Note**

No increase in the maximum number of repeats may be authorised.

**Note**

Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:

(a) a nurse educator/counsellor for patients; and

(b) 24-hour access by patients to medical advice; and

(c) an established liver clinic.

**Authority required**

Chronic non-genotype 1 hepatitis C infection

**Clinical criteria:**

The treatment must be the sole PBS-subsidised treatment for hepatitis C,

AND

Patient must have compensated liver disease,

AND

Patient must not have received prior interferon alfa or peginterferon alfa treatment for hepatitis C,

AND

The condition must be genotype 2, 3, 4, 5 or 6 hepatitis C,

AND

The treatment must be limited to a maximum duration of 24 weeks for patients with genotype 2 or 3 hepatitis C without hepatic cirrhosis or bridging fibrosis; OR

The treatment must be limited to a maximum duration of 48 weeks for patients with genotype 4, 5 or 6 hepatitis C; OR

The treatment must be limited to a maximum duration of 48 weeks for patients with genotype 2 or 3 hepatitis C with hepatic cirrhosis or bridging fibrosis,

AND

The treatment must cease in patients with genotype 4, 5, or 6 hepatitis C unless the results of an HCV RNA quantitative assay at week 12 (performed at the same laboratory using the same test) shows that plasma HCV RNA has become undetectable or the viral load has decreased by at least a 2 log
**HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)**

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<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>Qty $</th>
<th>Brand Name and Manufacturer</th>
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<tr>
<td>The treatment must cease in patients eligible for 48 weeks of treatment if HCV RNA is detectable by an HCV RNA qualitative assay at week 24.</td>
<td>Population criteria:</td>
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<tr>
<td>Patient must be aged 18 years or older,</td>
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<tr>
<td>Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.</td>
<td>Treatment criteria:</td>
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<tr>
<td>Must be treated in an accredited treatment centre.</td>
<td>Evidence of chronic hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient’s medical records.</td>
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<tr>
<td>Evidence of chronic hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient’s medical records.</td>
<td>For patients with genotype 4, 5, or 6 who are viral negative at week 12, an HCV RNA qualitative assay at week 24 is unnecessary.</td>
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<tr>
<td>For patients with genotype 2 or 3 without cirrhosis, an HCV RNA assay at week 12 is unnecessary because of the high likelihood of early viral response by week 12.</td>
<td>For patients who are eligible for 24 weeks of treatment, a maximum of 2 repeats may be prescribed.</td>
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<td>For patients who are eligible for 24 weeks of treatment, a maximum of 2 repeats may be prescribed.</td>
<td>For patients who are eligible for 48 weeks of treatment, a maximum of 5 repeats may be prescribed.</td>
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<tr>
<td>Caution</td>
<td>Treatment with peginterferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored.</td>
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<tr>
<td>Caution</td>
<td>Ribavirin is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and during the 6 months period after cessation of treatment.</td>
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<tr>
<td>Note</td>
<td>Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:</td>
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<tr>
<td>(a) a nurse educator/counsellor for patients; and</td>
<td>(b) 24-hour access by patients to medical advice; and</td>
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<td>(c) an established liver clinic.</td>
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<tr>
<td>6407F peginterferon alfa-2b 120 microgram injection [4 x 120 microgram cartridges] (&amp;) ribavirin 200 mg capsule [140 capsules] (&amp;) inert substance diluent [4 x 0.5 mL cartridges], 1 pack</td>
<td>2</td>
<td>5</td>
<td>..</td>
<td>*3538.34</td>
<td>Pegatron</td>
<td>MK</td>
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<td>6409H peginterferon alfa-2b 150 microgram injection [4 x 150 microgram cartridges] (&amp;) ribavirin 200 mg capsule [140 capsules] (&amp;) inert substance diluent [4 x 0.5 mL cartridges], 1 pack</td>
<td>2</td>
<td>5</td>
<td>..</td>
<td>*4126.28</td>
<td>Pegatron</td>
<td>MK</td>
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<td>6410J peginterferon alfa-2b 150 microgram injection [4 x 150 microgram cartridges] (&amp;) ribavirin 200 mg capsule [168 capsules] (&amp;) inert substance diluent [4 x 0.5 mL cartridges], 1 pack</td>
<td>2</td>
<td>5</td>
<td>..</td>
<td>*4126.28</td>
<td>Pegatron</td>
<td>MK</td>
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<td>9634C peginterferon alfa-2b 150 microgram injection [4 x 150 microgram cartridges] (&amp;) ribavirin 200 mg capsule [196 capsules] (&amp;) inert substance diluent [4 x 0.5 mL cartridges], 1 pack</td>
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<td>5</td>
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<td>*4411.24</td>
<td>Pegatron</td>
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<td>6402Y peginterferon alfa-2b 80 microgram injection [4 x 80 microgram cartridges] (&amp;) ribavirin 200 mg capsule [140 capsules] (&amp;) inert substance diluent [4 x 0.5 mL cartridges], 1 pack</td>
<td>2</td>
<td>5</td>
<td>..</td>
<td>*2754.42</td>
<td>Pegatron</td>
<td>MK</td>
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</tbody>
</table>

**Other immunostimulants**

**PLERIXAFOR**

**Authority required**

Mobilisation of haematopoietic stem cells

**Clinical criteria:**

The treatment must be in combination with granulocyte-colony stimulating factor (G-CSF),

**AND**

Patient must have lymphoma; OR

**AND**

Patient must have multiple myeloma,
Patient must require autologous stem cell transplantation,

AND

Patient must have failed previous stem cell collection; OR

Patient must be undergoing chemotherapy plus G-CSF mobilisation and their peripheral blood CD34+ count is less than 10,000 per millilitre or less than 10 million per litre on the day of planned collection; OR

Patient must be undergoing chemotherapy plus G-CSF mobilisation and the first apheresis has yielded less than 1 million CD34+ cells/kg.

Evidence that the patient meets the PBS restriction criteria must be recorded in the patient’s medical records.

Note

Applications for increased maximum quantities will only be authorised for patients with body weight greater than 100 kg.

10084R
plerixafor 24 mg/1.2 mL injection: subcutaneous infusion, 1 x 1.2 mL vial

IMMUNOSUPPRESSANTS

Selective immunosuppressants

ABATACEPT

Authority required

Initial 1 (new patient or patient re-commencing after a break of more than 24 months)

Initial PBS-subsidised treatment with abatacept, in combination with methotrexate at a dose of at least 7.5 mg weekly, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults who:

(a) have severe active rheumatoid arthritis; and

(b) have received no PBS-subsidised treatment with a bDMARD for this condition in the previous 24 months; and

(c) have failed, in the 24 months immediately prior to the date of application, to achieve an adequate response to at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs), which must include at least 3 months continuous treatment with at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be:

— hydroxychloroquine at a dose of at least 200 mg daily; or

— leflunomide at a dose of at least 10 mg daily; or

— sulfasalazine at a dose of at least 2 g daily.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, then the 6 months of intensive DMARD treatment must include at least 3 months continuous treatment with each of at least 2 of the DMARDs:

— hydroxychloroquine at a dose of at least 200 mg daily; and/or

— leflunomide at a dose of at least 10 mg daily; and/or

— sulfasalazine at a dose of at least 2 g daily.

The application must include details of the contraindication or intolerance to methotrexate. Details of the toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose can be found on the Medicare Australia website [www.medicareaustralia.gov.au].

If 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved product information or cannot be tolerated at the doses specified above, then one or more of the following DMARDs may be used in place of these agents in order to satisfy the requirement for a trial of 6 months of intensive DMARD therapy with at least 2 DMARDs taken continuously for at least 3 months each:

— azathioprine at a dose of at least 1 mg/kg per day; and/or

— cyclosporin at a dose of at least 2 mg/kg/day; and/or

— sodium aurothiomalate at a dose of 50 mg weekly.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances. Details of the toxicities, including severity, which will be accepted as a reason for substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial can be found on the Medicare Australia website [www.medicareaustralia.gov.au].

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance and dose for each DMARD must be provided in the authority application. Details of the toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy can be found on the Medicare Australia website [www.medicareaustralia.gov.au].
At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion. Up to a maximum of 4 repeats may be authorised. Where fewer than 4 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Assessment of a patient’s response to an initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to further treatment with abatacept.

Patients who fail to demonstrate a response to treatment with abatacept under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**Authority required**

Initial 2 (change or re-commencement after break of less than 24 months)

Initial course of PBS-subsidised treatment with abatacept, in combination with methotrexate at a dose of at least 7.5 mg weekly, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults who:

(a) have a documented history of severe active rheumatoid arthritis; and

(b) have received prior PBS-subsidised bDMARD treatment for this condition and are eligible to receive further bDMARD therapy.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website [www.medicareaustralia.gov.au]]; and

(3) a signed patient acknowledgement.

A maximum of 16 weeks of treatment will be authorised under this restriction.

Where fewer than 4 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Assessment of a patient’s response to an initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to further treatment with abatacept.

Patients who fail to demonstrate a response to treatment with abatacept under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.
Patients who fail to demonstrate a response to treatment with abatacept under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**Authority required**

Continuing treatment

Continuing PBS-subsidised treatment with abatacept, in combination with methotrexate at a dose of at least 7.5 mg weekly, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults:

(a) who have a documented history of severe active rheumatoid arthritis; and

(b) who have demonstrated an adequate response to treatment with abatacept; and

(c) whose most recent course of PBS-subsidised bDMARD treatment was with abatacept.

An adequate response to treatment is defined as:

- an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;
- AND either of the following:
  1. a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
  2. a reduction in the number of the following major active joints, from at least 4, by at least 50%:
     - elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
     - shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The authority application must be made in writing and must include:

1. a completed authority prescription form; and
2. a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

A maximum of 24 weeks of treatment will be approved under this restriction.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion. Up to a maximum of 5 repeats may be authorised.

Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

All applications for continuing treatment with abatacept must include a measurement of response to the prior course of therapy. This assessment must be provided to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with abatacept, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

Patients who fail to demonstrate a response to treatment with abatacept under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**Note**

Any queries concerning the arrangements to prescribe abatacept may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Further prescribing information (including Authority Application Forms) is on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe abatacept should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

**Note**

TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying anti-rheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab) and the T-cell co-stimulation modulator (abatacept).

 Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

PBS-subsidised abatacept, golimumab, infliximab and rituximab must be used in combination with methotrexate at a dose of at least 7.5 mg weekly.

Where a patient cannot tolerate 7.5 mg of methotrexate weekly, they are eligible to receive PBS-subsidised adalimumab, certolizumab pegol, etanercept and tocilizumab.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these conditions.
interchangeability arrangements:

— a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
— a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
— once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact Medicare Australia on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab and tocilizumab, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to Medicare Australia within 4 weeks.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:

Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient’s weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:

A further application may be submitted to Medicare Australia 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept patients:

Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

### Special Pricing Arrangements

**Note**

(1) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and Medicare Australia will assess response according to these revised baseline measurements.

(2) Swapping therapy.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

### Note

Special Pricing Arrangements apply.
<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>Qty $</th>
<th>Brand Name and Manufacturer</th>
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<tr>
<td>MYCOPHENOLATE</td>
<td>Authority required</td>
<td>Prophylaxis of renal allograft rejection</td>
<td>Treatment Phase: Management</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Clinical criteria:</td>
<td>The treatment must be under the supervision and direction of a transplant unit.</td>
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<td></td>
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<td></td>
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<tr>
<td></td>
<td>Authority required</td>
<td>WHO Class III, IV or V lupus nephritis</td>
<td>Treatment Phase: Management</td>
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<td></td>
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<tr>
<td></td>
<td>Clinical criteria:</td>
<td>The condition must be proven by biopsy.</td>
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<tr>
<td></td>
<td>Treatment criteria:</td>
<td>Must be treated by a nephrologist or in consultation with a nephrologist.</td>
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<tr>
<td></td>
<td>The name of the consulting nephrologist must be included in the patient medical records.</td>
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<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Caution</td>
<td>Careful monitoring of patients is mandatory.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Note</td>
<td>Management includes initiation, stabilisation and review of therapy as required.</td>
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<td>6369F</td>
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<td>5</td>
<td>298.70</td>
<td>Myfortic</td>
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</table>

| MYCOPHENOLATE | Authority required | Management of rejection, under the supervision and direction of a transplant unit, in patients receiving this drug for prophylaxis of renal allograft rejection. Management includes initiation, stabilisation and review of therapy as required |
| Authority required | Management of rejection, under the supervision and direction of a transplant unit, in patients receiving this drug for prophylaxis of cardiac allograft rejection. Management includes initiation, stabilisation and review of therapy as required |
| Caution | Careful monitoring of patients is mandatory. |
| Note | For item codes 6208R and 1837Q, pharmaceutical benefits that have the form capsule 250 mg are equivalent for the purposes of substitution. |
| 1837Q | mycophenolate Capsule 250 mg, 50 | 12 | 5 | 736.60 | a | Ceptolate | AF |
| 6208R | mycophenolate mofetil 250 mg capsule, 100 | 6 | 5 | 736.60 | a | APO-Mycophenolate | TX |
|   |   |   |   |   | a | Mycophenolate Sandoz | RO |
|   |   |   |   |   | a | Pharmacor | SZ |
|   |   |   |   |   | a | Mycophenolate 250 | CR |

| MYCOPHENOLATE | Authority required | Management of rejection, under the supervision and direction of a transplant unit, in patients receiving this drug for prophylaxis of renal allograft rejection. Management includes initiation, stabilisation and review of therapy as required |
| Authority required | Management of rejection, under the supervision and direction of a transplant unit, in patients receiving this drug for prophylaxis of cardiac allograft rejection. Management includes initiation, stabilisation and review of therapy as required |
| Caution | Careful monitoring of patients is mandatory. |
| Note | For item codes 6208R and 1837Q, pharmaceutical benefits that have the form capsule 250 mg are equivalent for the purposes of substitution. |
| 6364Y | mycophenolate mofetil 1 g/5 mL oral liquid: powder for, 165 mL | 2 | 5 | 517.97 | CellCept | RO |
| 6209T | mycophenolate mofetil 500 mg tablet, 50 | 6 | 5 | 736.60 | a | APO-Mycophenolate | TX |
|   |   |   |   |   | a | CellCept | RO |
|   |   |   |   |   | a | Ceptolate | AF |
|   |   |   |   |   | a | Mycophenolate Sandoz | SZ |
### Nataлизумаб
**Authority required**
Initial treatment, as monotherapy, by a neurologist, of clinically definite relapsing-remitting multiple sclerosis in an ambulatory (without assistance or support) patient 18 years of age or older, who has experienced at least 2 documented attacks of neurological dysfunction, believed to be due to multiple sclerosis, in the preceding 2 years.

The diagnosis must be confirmed by magnetic resonance imaging of the brain and/or spinal cord and the date of the scan included in the authority application, unless the authority application is accompanied by written certification provided by a radiologist that an MRI scan is contraindicated because of the risk of physical (not psychological) injury to the patient.

**Authority required**
Continuing treatment, as monotherapy, of clinically definite relapsing-remitting multiple sclerosis in a patient previously issued with an authority prescription for this drug who does not show continuing progression of disability while on treatment with this drug, and who has demonstrated compliance with, and an ability to tolerate, this therapy.

**Caution**
Progressive multifocal leukoencephalopathy has been reported with this drug.

**Note**
Neurologists prescribing natalizumab under the PBS listing must be registered with the Tysabri Australian Prescribing Program.

**Note**
Special Pricing Arrangements apply.

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty</th>
<th>No. of Rpts</th>
<th>Premium Qty $</th>
<th>Brand Name and Manufacturer</th>
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<td>9624M</td>
<td>natalizumab 300 mg/15 mL injection, 1 x 15 mL vial</td>
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<td>5</td>
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### Сиролимус
**Authority required**
Management of rejection, under the supervision and direction of a transplant unit, in patients receiving this drug for prophylaxis of renal allograft rejection. Management includes initiation, stabilisation and review of therapy as required.

**Caution**
Careful monitoring of patients is mandatory.

<table>
<thead>
<tr>
<th>Code</th>
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<th>Max. Qty</th>
<th>No. of Rpts</th>
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<td>6457W</td>
<td>sirolimus 2 mg tablet, 100</td>
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<td>sirolimus 500 microgram tablet, 100</td>
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### Tumor necrosis factor alpha (TNF-) inhibitors

### Адальimumаб
**Authority required**
Severe active juvenile idiopathic arthritis.

**Clinical criteria:**

- Patient must have severe active juvenile idiopathic arthritis.
- Patient must have received no prior PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition; or
- Patient must not have received PBS-subsidised treatment with adalimumab, etanercept or tocilizumab for this condition in the previous 12 months, and
- Patient must have demonstrated severe intolerance of, or toxicity due to, methotrexate; or
- Patient must have demonstrated failure to achieve an adequate response to 1 or more of the following treatment regimens: (i) oral or parenteral methotrexate at a dose of at least 20 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; or (ii) oral methotrexate at a dose of at least 10 mg per square metre weekly together with at least 1 other disease modifying anti-rheumatic drug (DMARD), alone or in combination with corticosteroids, for a minimum of 3 months, and
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be under 18 years of age and a parent or authorised guardian must have signed a patient acknowledgement.
### Treatment criteria:
- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.

Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.

Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis.

If treatment with methotrexate alone or in combination with another DMARD is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:
- (a) an active joint count of at least 20 active (swollen and tender) joints; OR
- (b) at least 4 active joints from the following list:
  - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
  - (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count assessment must be performed preferably whilst still on DMARD treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

The authority application must be made in writing and must include:
- (1) a completed authority prescription form; and
- (2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form; and
- (3) an acknowledgement signed by a parent or authorised guardian.

At the time of authority application, medical practitioners must request the appropriate number of injections of appropriate strength, based on the weight of the patient, to provide sufficient for two doses. Up to a maximum of 3 repeats will be authorised.

If a patient fails to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle. A patient may re-trial adalimumab after a minimum of 12 months have elapsed between the date the last PBS-subsidised bDMARD was stopped and the date of the first application under a new treatment cycle.

### Note
Use of alternative DMARDs in children is dependent on approval by the Therapeutic Goods Administration as age restrictions may apply.

### Note
Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
- Department of Human Services
- Prior Written Approval of Complex Drugs
- Reply Paid 9826
- GPO Box 9826
TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient who has severe active juvenile idiopathic arthritis. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.

From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised biological therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 12 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 12 months may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 12 months (Initial 1); or

(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or

(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 12 months in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 12 months.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.

(4) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 12 months, must requalify for treatment under the Initial 1 treatment restriction.

(5) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with bDMARDs should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to the Department of Human Services at the time treatment is ceased.

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after break of less than 12 months)

Clinical criteria:

Patient must have a documented history of severe active juvenile idiopathic arthritis,

AND

Patient must have received prior PBS-subsidised treatment with adalimumab, etanercept or tocilizumab for this condition in this treatment cycle,

AND

Patient must not have failed PBS-subsidised therapy with adalimumab for this condition in the current treatment cycle,

AND

Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

Patient must be under 18 years of age.

Treatment criteria:

Must be treated by a paediatric rheumatologist; OR

Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

For the purposes of this restriction ‘biological disease modifying anti-rheumatic drug’ and ‘bDMARD’ mean adalimumab, etanercept or tocilizumab.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners must request the appropriate number of injections of appropriate strength, based on the weight of the patient, to provide sufficient for two doses. Up to a maximum of 3 repeats will be authorised.

Applications for a patient who has received PBS-subsidised treatment with adalimumab in this treatment cycle and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient’s most recent course of PBS-subsidised adalimumab treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised adalimumab treatment was approved under either of the Initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised adalimumab treatment was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with adalimumab.

If a patient fails to respond to PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle.

An adequate response to treatment is defined as:
(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Note
Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Note
TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient who has severe active juvenile idiopathic arthritis. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.

From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised biological therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 12 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 12 months may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 12 months (Initial 1); or

(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or

(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 12 months in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have
Failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 12 months.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.

(4) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 12 months, must requalify for treatment under the Initial 1 treatment restriction.

(5) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with bDMARDs should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to the Department of Human Services at the time treatment is ceased.

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 12 months) or Initial 2 (change or recommencement of treatment after break of less than 12 months) – balance of supply

Clinical criteria:

Patient must have received insufficient adalimumab therapy under the Initial 1 (new patient or patient recommencing treatment after break of more than 12 months) restriction to complete 16 weeks treatment; OR

Patient must have received insufficient adalimumab therapy under the Initial 2 (change or recommencement of treatment after break of less than 12 months) restriction to complete 16 weeks treatment,

AND

The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Treatment criteria:

Must be treated by a paediatric rheumatologist; OR

Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Note

Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826
### HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

<table>
<thead>
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<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
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<td></td>
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**Authority required**
- Treatment Phase: Continuing treatment
- **Clinical criteria:**
  - Patient must have a documented history of severe active juvenile idiopathic arthritis,
  - Patient must have demonstrated an adequate response to treatment with adalimumab,
  - Patient must have received adalimumab as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment in this treatment cycle,
  - Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.
- **Treatment criteria:**
  - Must be treated by a rheumatologist; OR
  - Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

For the purposes of this restriction ‘biological disease modifying anti-rheumatic drug’ and ‘bDMARD’ mean adalimumab, etanercept or tocilizumab.

An adequate response to treatment is defined as:

- (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
- (b) a reduction in the number of the following active joints, from at least 4, by at least 50%:
  - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
  - (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurement of joint count submitted with the initial treatment application.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners must request the appropriate number of injections of appropriate strength, based on the weight of the patient, to provide sufficient for two doses. Up to a maximum of 5 repeats will be authorised.

All applications for continuing treatment with adalimumab must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with adalimumab, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with adalimumab.

If a patient fails to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle.

**Note**
- Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
- Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.

From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and
(ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised biological therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 12 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 12 months may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 12 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 12 months in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 12 months.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.

(4) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 12 months, must requalify for treatment under the Initial 1 treatment restriction.

(5) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with bDMARDs should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to the Department of Human Services at the time treatment is ceased.

**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment – balance of supply

**Clinical criteria:**

Patient must have received insufficient adalimumab therapy under the Continuing treatment restriction to complete 24 weeks treatment, AND

The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Treatment criteria:**

Must be treated by a rheumatologist; OR

Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

**Note**

Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

<table>
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<th>Code</th>
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<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
<th>Premium $</th>
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<td>1676.76</td>
<td>Humira VE</td>
</tr>
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</table>

**ETANERCEPT Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment

**Clinical criteria:**

Patient must have a documented history of severe active juvenile idiopathic arthritis, AND

Patient must have demonstrated an adequate response to treatment with etanercept, AND
### Code | Name, Restriction, Manner of Administration and Form | Max. Qty (Packs) | No. of Rpts | Premium $ | Qty | Brand Name and Manufacturer
---|---|---|---|---|---|---
Patient must have received etanercept as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment in this treatment cycle.

**AND**

Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

**Population criteria:**

Patient must be aged 18 years or older.

**Treatment criteria:**

Must be treated by a rheumatologist; OR

Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurement of joint count submitted with the initial treatment application.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

Where a patient with severe active juvenile idiopathic arthritis continues treatment with etanercept and is 18 years or older, etanercept 50 mg may be prescribed.

At the time of authority application, medical practitioners must request the appropriate number of injections to provide sufficient for four weeks of treatment. Up to a maximum of 5 repeats will be authorised.

All applications for continuing treatment with etanercept must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with etanercept, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with etanercept.

If a patient fails to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle.

**Note**

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

**Note**
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient who has severe active juvenile idiopathic arthritis. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.

From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised biological therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 12 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 12 months may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 12 months (Initial 1); or

(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or

(iv) a patient wishes to re-commence treatment with a specific PBS-subsidised bDMARD following a break of less than 12 months in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 12 months.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority...
prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.

(4) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 12 months, must requalify for treatment under the initial 1 treatment restriction.

(5) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with bDMARDs should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to the Department of Human Services at the time treatment is ceased.

Authority required
Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment – balance of supply

Clinical criteria:
Patient must have received insufficient etanercept therapy under the Continuing treatment restriction to complete 24 weeks treatment, AND
The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

Treatment criteria:
Must be treated by a rheumatologist; OR
Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Note
Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

9641K  
ETANERCEPT Injection 50 mg in 1 mL single use auto-injector, 4, 1  
1  ..  ..  1676.77  Enbrel  PF

9615C  
ETANERCEPT Injections 50 mg in 1 mL single use pre-filled syringes, 4, 1  
1  ..  ..  1676.77  Enbrel  PF

ETANERCEPT
Authority required
Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 12 months)

Clinical criteria:
Patient must have severe active juvenile idiopathic arthritis, AND
Patient must have received no prior PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition; OR
Patient must not have received PBS-subsidised treatment with adalimumab, etanercept or tocilizumab for this condition in the previous 12 months, AND
Patient must have demonstrated severe intolerance of, or toxicity due to, methotrexate; OR
Patient must have demonstrated failure to achieve an adequate response to 1 or more of the following treatment regimens: (i) oral or parenteral methotrexate at a dose of at least 20 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; or (ii) oral methotrexate at a dose of at least 10 mg per square metre weekly together with at least 1 other disease modifying anti-rheumatic drug (DMARD), alone or in combination with corticosteroids, for a minimum of 3 months, AND
Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:
Patient must be under 18 years of age and a parent or authorised guardian must have signed a patient acknowledgement.

Treatment criteria:

Must be treated by a paediatric rheumatologist; OR

Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.

Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.

Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis.

If treatment with methotrexate alone or in combination with another DMARD is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

(a) an active joint count of at least 20 active (swollen and tender) joints; OR
(b) at least 4 active joints from the following list:
   (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
   (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count assessment must be performed preferably whilst still on DMARD treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and
(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form; and
(3) an acknowledgement signed by a parent or authorised guardian.

At the time of authority application, medical practitioners must request the appropriate number of injections to provide sufficient for four weeks of treatment. Up to a maximum of 3 repeats will be authorised.

If a patient fails to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle. A patient may re-trial etanercept after a minimum of 12 months have elapsed between the date the last PBS-subsidised bDMARD was stopped and the date of the first application under a new treatment cycle.

Note

Use of alternative DMARDs in children is dependent on approval by the Therapeutic Goods Administration as age restrictions may apply.

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826
### TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient who has severe active juvenile idiopathic arthritis. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.

From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD only,

Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised biological therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the initial application for initial treatment with a bDMARD under the new treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 12 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 12 months may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle. There is no limit to the number of treatment cycles a patient may undertake.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 12 months (Initial 1); or

(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or

(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 12 months in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 12 months.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within

### Table: PBS-subsidised Biological Therapy Requirements

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</table>
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.

(4) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 12 months, must requalify for treatment under the Initial 1 treatment restriction.

(5) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with bDMARDs should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to the Department of Human Services at the time treatment is ceased.

**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after break of less than 12 months)

**Clinical criteria:**

Patient must have a documented history of severe active juvenile idiopathic arthritis,

AND

Patient must have received prior PBS-subsidised treatment with adalimumab, etanercept or tocilizumab for this condition in this treatment cycle,

AND

Patient must not have failed PBS-subsidised therapy with etanercept for this condition in the current treatment cycle,

AND

Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

Patient must be under 18 years of age.

**Treatment criteria:**

Must be treated by a paediatric rheumatologist; OR

Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.

The authority application must be made in writing and must include:

1. a completed authority prescription form; and
2. a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners must request the appropriate number of injections to provide sufficient for four weeks of treatment. Up to a maximum of 3 repeats will be authorised.

Applications for a patient who has received PBS-subsidised treatment with etanercept in this treatment cycle and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised etanercept treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised etanercept treatment was approved under either of the Initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised etanercept treatment was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with etanercept.

If a patient fails to respond to PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle.
An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Note

TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient who has severe active juvenile idiopathic arthritis. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.

From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised biological therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 12 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 12 months may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 12 months (Initial 1); or

(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or

(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 12 months in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 12 months, (4) re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

Response according to the revised baseline measurement.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 12 months.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement at any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.

(4) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 12 months, must requalify for treatment under the initial 1 treatment restriction.

(5) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with bDMARDs should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to the Department of Human Services at the time treatment is ceased.

**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 12 months) or Initial 2 (change or recommencement of treatment after break of less than 12 months) – balance of supply

**Clinical criteria:**

Patient must have received insufficient etanercept therapy under the Initial 1 (new patient or patient recommencing treatment after break of more than 12 months) restriction to complete 16 weeks treatment; OR

Patient must have received insufficient etanercept therapy under the Initial 2 (change or recommencement of treatment after break of less than 12 months) restriction to complete 16 weeks treatment,

**AND**

The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Treatment criteria:**

Must be treated by a paediatric rheumatologist; OR

Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

**Note**

Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs
Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment

Clinical criteria:
- Patient must have a documented history of severe active juvenile idiopathic arthritis,
- Patient must have demonstrated an adequate response to treatment with etanercept,
- Patient must have received etanercept as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment in this treatment cycle,
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

Treatment criteria:
- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:
   (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
   (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurement of joint count submitted with the initial treatment application.

The authority application must be made in writing and must include:
1. a completed authority prescription form; and
2. a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners must request the appropriate number of injections to provide sufficient for four weeks of treatment. Up to a maximum of 5 repeats will be authorised.

All applications for continuing treatment with etanercept must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with etanercept, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with etanercept.

If a patient fails to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle.

Note
Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of

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**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment

Patient must have a documented history of severe active juvenile idiopathic arthritis,

AND

Patient must have demonstrated an adequate response to treatment with etanercept,

AND

Patient must have received etanercept as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment in this treatment cycle,

AND

Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:
   (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
   (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The authority application must be made in writing and must include:
1. a completed authority prescription form; and
2. a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners must request the appropriate number of injections to provide sufficient for four weeks of treatment. Up to a maximum of 5 repeats will be authorised.

All applications for continuing treatment with etanercept must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with etanercept, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with etanercept.

If a patient fails to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle.

Note
Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of
TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient who has severe active juvenile idiopathic arthritis. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.

From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised biological therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 12 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 12 months may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 12 months (Initial 1); or

(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or

(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 12 months in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to reaffirm with respect to the indices of disease severity (joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 12 months.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.

(4) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 12 months, must requalify for treatment under the Initial 1 treatment restriction.

(5) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with bDMARDs should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to the Department of Human Services at the time treatment is ceased.

**Authority required**

Severe active juvenile idiopathic arthritis

**Treatment Phase:** Continuing treatment – balance of supply

**Clinical criteria:**

Patient must have received insufficient etanercept therapy under the Continuing treatment restriction to complete 24 weeks treatment, AND

The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Treatment criteria:**

Must be treated by a rheumatologist; OR

Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

**Note**

Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

etanercept 25 mg injection [4 x 25 mg vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack

\[
\begin{array}{|c|c|c|c|c|c|}
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\text{Code} & \text{Name, Restriction, Manner of Administration and Form} & \text{Max. Qty} & \text{No. of Rpts} & \text{Premium Qty} & \text{Brand Name and Manufacturer} \\
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6367D & \text{etanercept 25 mg injection [4 x 25 mg vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack} & 1 & . & . & 854.36 \text{ Enbrel PF} \\
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**INFLIXIMAB**

**Authority required**

Acute severe ulcerative colitis

**Clinical criteria:**

Patient must have received an infusion of infliximab for the treatment of this condition as a hospital inpatient no more than two weeks prior to the date of the authority application, AND

Patient must be an adult aged 18 years or older, and prior to initiation of infliximab treatment in hospital must have been experiencing six or more bloody stools per day, plus at least one of the following: (i) Temperature greater than 37.8 degrees Celsius; (ii) Pulse rate greater than 90 beats per minute; (iii) Haemoglobin less than 105 g/L; (iv) Erythrocyte sedimentation rate greater than 30 mm/h; OR

Patient must be a child aged 6 to 17 years inclusive, and prior to initiation of infliximab treatment in hospital must have had a Paediatric Ulcerative Colitis Activity Index (PUCAI) greater than or equal to 65, with the diagnosis confirmed by a gastroenterologist, or a consultant physician as specified.
**INFLIXIMAB**

**Authority required**

Initial PBS-subsidised treatment with infliximab, in combination with methotrexate at a dose of at least 7.5 mg weekly, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults who:

(a) have severe active rheumatoid arthritis; and  
(b) have received no PBS-subsidised treatment with a bDMARD for this condition in the previous 24 months; and  
(c) have failed, in the 24 months immediately prior to the date of application, to achieve an adequate response to at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs), which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be:

- hydroxychloroquine at a dose of at least 200 mg daily; or  
- leflunomide at a dose of at least 10 mg daily; or  
- sulfasalazine at a dose of at least 2 g daily.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, then the 6 months of intensive DMARD treatment must include at least 3 months continuous treatment with each of at least 2 of the DMARDs:

- hydroxychloroquine at a dose of at least 200 mg daily; and/or  
- leflunomide at a dose of at least 10 mg daily; and/or  
- sulfasalazine at a dose of at least 2 g daily.

The application must include details of the contraindication or intolerance to methotrexate. Details of the toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose can be found on the Medicare Australia website [www.medicareaustralia.gov.au]. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.
Patients who fail to demonstrate a response to treatment with infliximab under this restriction will not be eligible to receive further PBS-subsidised infliximab.

If 3 or more of methotrexate, hydroxychloroquine, lefunomide and sulfasalazine are contraindicated according to the relevant TGA-approved product information or cannot be tolerated at the doses specified above, then one or more of the following DMARDs may be used in place of these agents in order to satisfy the requirement for a trial of 6 months of intensive DMARD therapy with at least 2 DMARDs taken continuously for at least 3 months each:

- azathioprine at a dose of at least 1 mg/kg per day; and/or
- cyclosporin at a dose of at least 2 mg/kg/day; and/or
- sodium aurothiomalate at a dose of 50 mg weekly.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances. Details of the toxicities, including severity, which will be accepted as a reason for substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial can be found on the Medicare Australia website [www.medicareaustralia.gov.au].

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance and dose for each DMARD must be provided in the authority application. Details of the toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy can be found on the Medicare Australia website [www.medicareaustralia.gov.au].

If 3 or more of methotrexate, hydroxychloroquine, lefunomide and sulfasalazine are contraindicated according to the relevant TGA-approved product information or cannot be tolerated at the doses specified above, then one or more of the following DMARDs may be used in place of these agents in order to satisfy the requirement for a trial of 6 months of intensive DMARD therapy with at least 2 DMARDs taken continuously for at least 3 months each:

- azathioprine at a dose of at least 1 mg/kg per day; and/or
- cyclosporin at a dose of at least 2 mg/kg/day; and/or
- sodium aurothiomalate at a dose of 50 mg weekly.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances. Details of the toxicities, including severity, which will be accepted as a reason for substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial can be found on the Medicare Australia website [www.medicareaustralia.gov.au].

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

- an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either
  (i) a total active joint count of at least 20 active (swollen and tender) joints; or
  (ii) at least 4 active joints from the following list of major joints:
    - elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
    - shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

1. a completed authority prescription form; and
2. a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website [www.medicareaustralia.gov.au]]; and
3. a signed patient acknowledgement.

A maximum of 22 weeks of treatment will be authorised under this restriction.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 3 mg per kg. Up to a maximum of 3 repeats may be authorised. Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 22 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Assessment of a patient's response to an initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

Patients who fail to demonstrate a response to treatment with infliximab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition

**Authority required**

Initial 2 (change or re-commencement after break of less than 24 months)

Initial course of PBS-subsidised treatment with infliximab, in combination with methotrexate at a dose of at least 7.5 mg weekly, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults who:

(a) have a documented history of severe active rheumatoid arthritis; and

(b) have received prior PBS-subsidised bDMARD treatment for this condition and are eligible to receive further bDMARD therapy.

The authority application must be made in writing and must include:

<table>
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<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty</th>
<th>No. of Rpts</th>
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- sodium aurothiomalate at a dose of 50 mg weekly.
- cyclosporin at a dose of at least 2 mg/kg/day; and/or
- sodium aurothiomalate at a dose of 50 mg weekly.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances. Details of the toxicities, including severity, which will be accepted as a reason for substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial can be found on the Medicare Australia website [www.medicareaustralia.gov.au].

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

- an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either
  (i) a total active joint count of at least 20 active (swollen and tender) joints; or
  (ii) at least 4 active joints from the following list of major joints:
    - elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
    - shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

1. a completed authority prescription form; and
2. a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website [www.medicareaustralia.gov.au]]; and
3. a signed patient acknowledgement.

A maximum of 22 weeks of treatment will be authorised under this restriction.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 3 mg per kg. Up to a maximum of 3 repeats may be authorised. Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 22 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Assessment of a patient's response to an initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

Patients who fail to demonstrate a response to treatment with infliximab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition

**Authority required**

Initial 2 (change or re-commencement after break of less than 24 months)

Initial course of PBS-subsidised treatment with infliximab, in combination with methotrexate at a dose of at least 7.5 mg weekly, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults who:

(a) have a documented history of severe active rheumatoid arthritis; and

(b) have received prior PBS-subsidised bDMARD treatment for this condition and are eligible to receive further bDMARD therapy.

The authority application must be made in writing and must include:
At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 3 mg per kg. Up to a maximum of 3 repeats may be authorised.

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 22 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Where the most recent course of PBS-subsidised infliximab treatment was approved under either of the initial 1 or 2 treatment restrictions, patients must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be provided to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised infliximab treatment was approved under the continuing treatment criteria, patients must have been assessed for response, and the assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Patients who fail to demonstrate a response to treatment with infliximab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition

**Authority required**

Continuing treatment

Continuing PBS-subsidised treatment with infliximab, in combination with methotrexate at a dose of at least 7.5 mg weekly, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults:

(a) who have a documented history of severe active rheumatoid arthritis; and

(b) who have demonstrated an adequate response to treatment with infliximab; and

(c) whose most recent course of PBS-subsidised bDMARD treatment was with infliximab.

An adequate response to treatment is defined as:

- an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following:
  - (i) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
  - (ii) a reduction in the number of the following major active joints, from at least 4, by at least 50%:
    - elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
    - shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

A maximum of 24 weeks of treatment will be approved under this restriction.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 3 mg per kg. Up to a maximum of 2 repeats may be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

All applications for continuing treatment with infliximab must include a measurement of response to the prior course of therapy. This assessment must be provided to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with infliximab, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

Patients who fail to demonstrate a response to treatment with infliximab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition

**Note**

Any queries concerning the arrangements to prescribe infliximab may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe infliximab should be forwarded to:

Medicare Australia
TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying anti-rheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab) and the T-cell co-stimulation modulator (abatacept).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time. PBS-subsidised abatacept, golimumab, infliximab and rituximab must be used in combination with methotrexate at a dose of at least 7.5 mg weekly. Where a patient cannot tolerate 7.5 mg of methotrexate weekly, they are eligible to receive PBS-subsidised adalimumab, certolizumab pegol, etanercept and tocilizumab.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:

(a) a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,

(b) a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and

(c) once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact Medicare Australia on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or

(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or

(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or

(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab and tocilizumab, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to Medicare Australia within 4 weeks.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:

Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient’s weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial...
Rituximab patients:

A further application may be submitted to Medicare Australia 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to submitting their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate [ESR], the C-reactive protein [CRP] levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept patients:

Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

Note
(3) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and Medicare Australia will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Note
Special Pricing Arrangements apply.

6397Q infliximab 100 mg injection, 1 x 100 mg vial 1 .. .. 788.53 Remicade JC
INFLIXIMAB

**Authority required**
Active ankylosing spondylitis
Treatment Phase: Initial 1 (new patients)

**Clinical criteria:**
The condition must be radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis,

AND
Patient must not have received any PBS-subsidised treatment with either adalimumab, certolizumab pegol, etanercept, golimumab or infliximab in this treatment cycle,

AND
Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; or (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); or (iii) limitation of chest expansion relative to normal values for age and gender,

AND
Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months.

**Population criteria:**
Patient must be an adult.

**Treatment criteria:**
Must be treated by a rheumatologist.
The application must include details of the NSAIDs trialled, their doses and duration of treatment.
If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used.
If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication.
If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance.
The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application:
(a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; AND
(b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L.
The BASDAI must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. The BASDAI must be no more than 1 month old at the time of initial application.
Both ESR and CRP measures should be provided with the initial treatment application and both must be no more than 1 month old. If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied.
The authority application must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form which must include the following:
(i) a copy of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and
(ii) a completed BASDAI Assessment Form; and
(iii) a completed Exercise Program Self Certification Form included in the supporting information form; and
(iv) a signed patient acknowledgment.
The assessment of the patient's response to the initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted no later than 4 weeks from the cessation of that treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.
A maximum of 18 weeks of treatment with this drug will be approved under this criterion.
At the time of authority application, the doctor should request the appropriate number of vials, based on the weight of the patient, to provide for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.
Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) was approved in this cycle and the date of the first application under a new cycle.

**Note**
Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Department of Human Services website at www.humanservices.gov.au

**Note**
## Authority required

**Ankylosing spondylitis**

**Treatment Phase:** Initial 2 (change or recommencement for all patients)

**Clinical criteria:**

- Patient must have a documented history of active ankylosing spondylitis,
- AND
- Patient must have received prior PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition in this treatment cycle,
- AND
- Patient must not have failed PBS-subsidised therapy with this drug for this condition in the current treatment cycle,
- AND
- Patient must be eligible to receive further bDMARD therapy.

**Population criteria:**

- Patient must be an adult.

**Treatment criteria:**

- Must be treated by a rheumatologist.

Where the most recent course of PBS-subsidised bDMARD treatment was approved under either of the initial treatment restrictions (i.e. for patients with no prior PBS-subsidised bDMARD therapy or, under this restriction, for patients who have received previous PBS-subsidised bDMARD therapy) the patient must have been assessed for response to that course following a minimum of 12 weeks of treatment. These assessments must be provided to the Department of Human Services no later than 4 weeks from the date the course was ceased. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, patients must have been assessed for response, and the assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form.

A maximum of 18 weeks of treatment with this drug will be approved under this criterion.

At the time of authority application, the doctor should request the appropriate number of vials, based on the weight of the patient, to provide for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.

Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised bDMARD was approved in this cycle and the date of the first application under a new cycle.

**Note**

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

- Department of Human Services
- Prior Written Approval of Complex Drugs
- Reply Paid 9826
- GPO Box 9826
- HOBART TAS 7001

**Note**

TREATMENT OF ADULT PATIENTS WITH ACTIVE ANKYLOSING SPONDYLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, certolizumab pegol, etanercept, golimumab and infliximab for adult patients with active ankylosing spondylitis.

Where the term 'bDMARD' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 5 bDMARDs at any 1 time.

From 1 March 2007, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised bDMARDs without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a bDMARD while they continue to show a response to therapy.
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the BASDAI, ESR and/or CRP, as well as additional data submitted with each initial or continuing treatment application. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements.

For a new patient, the BASDAI used to determine the baseline must be measured while the patient is receiving NSAID treatment, as well as completing their current course of treatment. For second and subsequent courses of PBS-subsidised bDMARD treatment, it is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

To avoid confusion, an application for a patient who wishes to switch to another bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements.

For a new patient, the BASDAI used to determine the baseline must be measured while the patient is receiving NSAID treatment and completing their exercise program.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with at least 1 NSAID, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the BASDAI, ESR and/or CRP levels are measured.

Authority required
Ankylosing spondylitis

Treatment Phase: Initial treatment – Initial 1 (new patients) or Initial 2 (change or recommencement for all patients) – balance of supply

Clinical criteria:
Patient must have active, or a documented history of active, ankylosing spondylitis,

AND
Patient must have received insufficient therapy with this drug under the Initial 1 (new patients) restriction to complete 18 weeks treatment; OR
Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement for all patients) restriction to complete 18 weeks treatment,

AND
The treatment must provide no more than the balance of up to 18 weeks treatment available under the above restrictions.

Population criteria:
Patient must be an adult.

Treatment criteria:
Must be treated by a rheumatologist.

Note
Authority approval for sufficient therapy to complete a maximum of 18 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 18 weeks of treatment should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Authority required
Ankylosing spondylitis

Treatment Phase: Continuing treatment

Clinical criteria:
Patient must have a documented history of active ankylosing spondylitis,

AND
Patient must have received this drug as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment in this treatment cycle,

AND
Patient must have demonstrated an adequate response to treatment with this drug.

Population criteria:
Patient must be an adult.

Treatment criteria:
Must be treated by a rheumatologist.

An adequate response is defined as an improvement from baseline of at least 2 of the BASDAI and 1 of the following:
(a) an ESR measurement no greater than 25 mm per hour; or
(b) a CRP measurement no greater than 10 mg per L; or
(c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and supplied in all subsequent continuing treatment applications.

The authority application must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form.

All measurements provided must be no more than 1 month old at the time of application.

A maximum of 24 weeks of treatment with this drug will be authorised under this criterion.

At the time of authority application, the doctor should request the appropriate number of vials, based on the weight of the patient, to provide for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.

All applications for continuing treatment with this drug must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment following an initial treatment course it must be made following a minimum of 12 weeks of treatment with this drug. If the response
Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised bDMARD was approved in this cycle and the date of the first application under a new cycle.

Note
Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
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TREATMENT OF ADULT PATIENTS WITH ACTIVE ANKYLOSING SPONDYLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, certolizumab pegol, etanercept, golimumab and infliximab for adult patients with active ankylosing spondylitis.

Where the term 'bDMARD' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 5 bDMARDs at any 1 time.

From 1 March 2007, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised bDMARDs without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a bDMARD while they continue to show a response to therapy.

A patient who received PBS-subsidised bDMARD treatment prior to 1 March 2007 is considered to be in their first cycle as of 1 March 2007.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once. A patient who, prior to 1 March 2007, was authorised to receive PBS-subsidised initial treatment for ankylosing spondylitis with the same agent twice, is exempt from this condition in respect of applications approved prior to 1 March 2007.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised bDMARD therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised bDMARD treatment in the most recent cycle to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or

(iii) a patient wishes to re-commence treatment with a specific bDMARD following a break in PBS-subsidised therapy with that agent (Initial 2).

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current course of treatment.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

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<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
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Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI), or the prior NSAID therapy and exercise program requirements.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements.

For a new patient, the BASDAI used to determine the baseline must be measured while the patient is receiving NSAID therapy and completing their exercise program.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with at least 1 NSAID, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the BASDAI, ESR and/or CRP levels are measured.

**Authority required**

Ankylosing spondylitis

Treatment Phase: Continuing treatment – balance of supply

Clinical criteria:

- Patient must have a documented history of active ankylosing spondylitis,

AND

- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment,

AND

- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

Population criteria:

- Patient must be an adult.

Treatment criteria:

- Must be treated by a rheumatologist.

**Note**

Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

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**INFIXIMAB**

**Authority required**

Initial 1

Initial PBS-subsidised treatment with infliximab, by a rheumatologist or clinical immunologist with expertise in the management of psoriatic arthritis, of adults who:

1. have severe active psoriatic arthritis; and

2. have received no prior PBS-subsidised biological treatment for this condition in this Treatment Cycle; and
If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity to necessitate permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of acceptable toxicities, including severity, can be found on the Medicare Australia website (www.medicareaustralia.gov.au).

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

- an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND

- either
  - (i) an active joint count of at least 20 active (swollen and tender) joints; or
  - (ii) at least 4 active joints from the following list of major joints:
    - elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
    - shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:

1. a completed authority prescription form; and
2. a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and
3. a signed patient acknowledgement.

A maximum of 22 weeks of treatment will be authorised under this restriction.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats may be authorised.

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 22 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

The assessment of the patient’s response to the initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Patients who fail to demonstrate a response to treatment with infliximab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug, in this Treatment Cycle. Patients may re-trial infliximab after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

**Authority required**

Initial 2

Initial PBS-subsidised treatment with infliximab, by a rheumatologist or clinical immunologist with expertise in the management of psoriatic arthritis, of adults who:

1. have a documented history of severe active psoriatic arthritis; and
2. have received prior PBS-subsidised biological treatment for this condition in this Treatment Cycle and are eligible to receive further biological therapy; and
3. have not failed treatment with infliximab during the current Treatment Cycle.

Applications for patients who have received PBS-subsidised treatment with infliximab within this Treatment Cycle and who wish to re-commence therapy with this drug within this same Cycle, must be accompanied by evidence of a response to the patient’s most recent course of PBS-subsidised infliximab treatment, within the timeframes specified below.

A maximum of 22 weeks treatment will be authorised under this restriction.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats may be authorised.

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 22 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Where the most recent course of PBS-subsidised infliximab treatment was approved under either of the initial treatment restrictions (i.e. for patients with no prior PBS-subsidised biological therapy or, under this restriction, for patients who have received previous PBS-subsidised biological therapy), patients must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be provided to Medicare Australia no later than 4 weeks from the date that course was ceased.
A maximum of 24 weeks of treatment will be approved under this restriction. The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

Patients who fail to demonstrate a response to treatment with infliximab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug, in this Treatment Cycle. Patients may re-trial infliximab after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle Authority required

Continuing treatment

Continuing PBS-subsidised treatment with infliximab, by a rheumatologist or clinical immunologist with expertise in the management of psoriatic arthritis, of adults:

(1) who have a documented history of severe active psoriatic arthritis; and

(2) whose most recent course of PBS-subsidised biological agent for this condition in the current Treatment Cycle was with infliximab; and

(3) who, at the time of application, demonstrate an adequate response to treatment with infliximab.

An adequate response to treatment with infliximab is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following:

(i) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(ii) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

— elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

— shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

A maximum of 24 weeks of treatment will be approved under this restriction.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats may be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

All applications for continuing treatment with infliximab must include a measurement of response to the prior course of therapy. This assessment must be provided to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with infliximab, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with the initial treatment course.

Patients who fail to demonstrate a response to treatment with infliximab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug, in this Treatment Cycle. Patients may re-trial infliximab after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle Note

Any queries concerning the arrangements to prescribe infliximab may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe infliximab should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

Note

TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents (adalimumab, etanercept, golimumab and infliximab) for adult patients with severe active psoriatic arthritis.

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological agents at any 1 time. Where the term ‘biological agents’...
From 1 August 2006, all patients will be able to commence a ‘Biological Treatment Cycle’ (Cycle), where they may trial biological agents without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

Following demonstration of response to initial treatment, these biological agents are available under the PBS for continuing treatment as set out in the continuing treatment restriction for each agent.

Once patients have either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological therapy before they are eligible to commence another Cycle (further details are under ‘(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy’ below).

The 5-year break in therapy will be measured from the date the last approval for PBS-subsidised treatment was granted in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Cycle.

Within the same Cycle, patients are not allowed to fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for any biological agent, they must change to an alternate agent which they have not previously failed, if they wish to continue PBS-subsidised biological treatment.

Patients for whom a break in PBS-subsidised therapy of less than 5 years has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle. Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle.

There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe active psoriatic arthritis after 1 August 2010.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); and

(ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; and

(iii) patients wish to re-commence treatment with a specific biological agent following a break in PBS-subsidised therapy with that specific agent (Initial 2).

All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of therapy for all agents except for infliximab, for which a maximum of 22 weeks will be authorised. It is recommended that patients be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological agent supply.

Patients must be assessed for response to any course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

Grandfather patients — golimumab only.

Applications for patients who commenced treatment with golimumab prior to 1 March 2010 may apply for initial PBS-subsidised treatment as continuing therapy under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with any biological agent prior to PBS listing of that agent.

Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment for all agents. Approval will be based on the criteria included in the relevant restriction.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological agent, patients may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. Patients are eligible to receive continuing biological treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

Patients must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

(3) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate biological agent without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements.

Patients may swap to an alternate biological agent at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological agent at the time of the application or not.

Patients may alternate between therapy with any biological agent of their choice (1 at a time) providing:

(i) they have not received PBS-subsidised treatment with that particular biological agent previously; or

(ii) they have demonstrated an adequate response to that particular biological agent if they have previously trialled it on the PBS; or

(iii) they have not previously failed to respond to treatment 3 times in this Treatment Cycle.

To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the biological agent the patient is ceasing.

(4) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the indices of disease severity submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment authority is submitted within a treatment cycle and Medicare Australia will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

Patients who wish to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must re-qualify for initial treatment with respect to both the indices of disease severity. Patients must have received treatment with methotrexate and sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the indices of disease severity submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment authority is submitted within a treatment cycle and Medicare Australia will assess response according to these revised baseline measurements.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, please consult a gastroenterologist or consultant physician as specified in the NOTE below.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [general medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, please consult a gastroenterologist or consultant physician as specified in the NOTE below.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [general medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, please consult a gastroenterologist or consultant physician as specified in the NOTE below.

The following initiation criterion indicates failure to achieve an adequate response and must be demonstrated in all patients at the time of the application:

(a) has confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or consultant physician as specified in the NOTE below; and

(b) whose parent or authorised guardian has signed a patient acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and

(c) has failed to achieve an adequate response to 2 of the following 3 conventional prior therapies including:

(i) a tapered course of steroids, starting at a dose of at least 1 mg per kg or 40 mg (whichever is the lesser) prednisolone (or equivalent), over a 6 week period;

(ii) an 8 week course of enteral nutrition;

(iii) immunosuppressive therapy including:

— azathioprine at a dose of at least 2 mg per kg daily for 3 or more months; or

— 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months; or

— methotrexate at a dose of at least 10 mg per square metre weekly for 3 or more months.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [general medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, please consult a gastroenterologist or consultant physician as specified in the NOTE below.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please consult a gastroenterologist or consultant physician as specified in the NOTE below.

The following initiation criterion indicates failure to achieve an adequate response and must be demonstrated in all patients at the time of the application:

(a) severity of disease activity which results in a Paediatric Crohn Disease Activity Index (PCDAI) Score greater than or equal to 30 as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

(b) The most recent PCDAI assessment must be no more than 1 month old at the time of application.

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website [www.medicareaustralia.gov.au]] which includes the following:

(i) the completed current Paediatric Crohn Disease Activity Index (PCDAI) calculation sheet including the date of assessment of the patient’s condition; and

(ii) details of previous systemic drug therapy [dosage, date of commencement and duration of therapy], or dates of enteral nutrition; and
A maximum quantity and number of repeats to provide for an initial course of infliximab consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of infliximab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

A PCDAI assessment of the patient’s response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment.

**Authority required**

Continuing treatment of Crohn disease in a patient initiated on PBS-subsidised treatment as a paediatric patient.

Continuing PBS-subsidised treatment with infliximab by a gastroenterologist, paediatrician, consultant physician as specified in the NOTE below or other consultant physician in consultation with a gastroenterologist, of a patient who:

(a) has a documented history of moderate to severe refractory Crohn disease; and

(b) has demonstrated or sustained an adequate response to treatment with infliximab.

**NOTE:** Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

An adequate response to infliximab treatment is defined as a reduction in Paediatric Crohn Disease Activity Index (PCDAI) Score by at least 15 points as compared to baseline AND a total PCDAI score of 30 points or less.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) the completed Paediatric Crohn Disease Activity Index (PCDAI) calculation sheet along with the date of the assessment of the patient’s condition.

The PCDAI assessment must be no more than 1 month old at the time of application.

If the application is the first application for continuing treatment with infliximab, a PCDAI assessment of the patient’s response must be made up to 12 weeks after the first dose so that there is adequate time for a response to be demonstrated.

The assessment of the patient’s response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with infliximab.

Patients are eligible to receive continuing infliximab treatment in courses of up to 24 weeks providing they continue to sustain the response.

Patients who fail to demonstrate or sustain a response to treatment with infliximab for Crohn disease as specified in the criteria for continuing treatment with infliximab, will not be eligible to receive PBS-subsidised treatment with this drug within 12 months of the date on which treatment was ceased.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised. No applications for increased repeats will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Authority required**

Initial PBS-subsidised treatment of Crohn disease in a paediatric patient who has previously received non-PBS-subsidised therapy with infliximab.

Initial PBS-subsidised supply for continuing treatment with infliximab by a gastroenterologist, paediatrician, consultant physician as specified in the NOTE below or other consultant physician in consultation with a gastroenterologist, of a patient aged 6 to 17 years inclusive who:

(a) has a documented history of moderate to severe refractory Crohn disease and was receiving treatment with infliximab prior to 4 July 2007; and

(b) had a Paediatric Crohn Disease Activity Index (PCDAI) Score of greater than 30 prior to commencing treatment with infliximab. Where a baseline CDAI assessment is not available, please call Medicare Australia on 1800 700 270 to discuss; and

(c) whose parent or authorised guardian has signed a patient acknowledgement indicating that they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and

(d) has demonstrated or sustained an adequate response to treatment with infliximab. For advice please contact Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

An adequate response to infliximab treatment is defined as a reduction in Paediatric Crohn Disease Activity Index (PCDAI) Score by at least 15 points as compared to baseline AND a total PCDAI score of 30 points or less.

Applications for authorisation must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) the completed current and baseline Paediatric Crohn Disease Activity Index (PCDAI) calculation sheet along with the date of the assessment of the patient’s condition; and
(ii) the signed patient acknowledgement.

The current PCDAI assessment must be no more than 1 month old at the time of application. The baseline PCDAI assessment must be from immediately prior to commencing treatment with infliximab.

The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, with infliximab.

Patients are eligible to receive continuing infliximab treatment in courses of up to 24 weeks providing they continue to sustain the response. Patients who fail to demonstrate or sustain a response to treatment with infliximab for Crohn disease as specified in the criteria for continuing treatment with infliximab, will not be eligible to recommence PBS-subsidised treatment with this drug within 12 months of the date on which treatment was ceased.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised. No applications for increased repeats will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Patients may qualify for PBS-subsidised treatment under this restriction once only

Note
Any queries concerning the arrangements to prescribe infliximab may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe infliximab should be forwarded to:
Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

9612X infliximab 100 mg injection, 1 x 100 mg vial 1 .. . 788.53 Remicade JC

INFLIXIMAB
Authority required
Initial 1 (new patients)

Initial treatment of Crohn disease in a patient assessed by CDAI.

Initial PBS-subsidised treatment with infliximab by a gastroenterologist or a consultant physician as specified in the NOTE below, of a patient with severe refractory Crohn disease who satisfies the following criteria:

(a) has confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician as specified in the NOTE below; and

(b) has signed a patient acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and

(c) has failed to achieve an adequate response to prior systemic therapy including:

(i) a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period; and

(ii) immunosuppressive therapy including:
— azathioprine at a dose of at least 2 mg per kg daily for 3 or more months; or
— 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months; or
NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of the accepted toxicities including severity can be found on the Medicare Australia website (www.medicareaustralia.gov.au).

The following initiation criterion indicates failure to achieve an adequate response and must be demonstrated in all patients at the time of the application:

(a) have a severity of disease activity which results in a Crohn Disease Activity Index (CDAI) Score greater than or equal to 300 as assessed.

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

The most recent CDAI assessment must be no more than 1 month old at the time of application.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and
(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) the completed current Crohn Disease Activity Index (CDAI) calculation sheet including the date of assessment of the patient’s condition; and
(ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and
(iii) the signed patient acknowledgement.

A maximum quantity and number of repeats to provide for an initial course of infliximab consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of infliximab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

A CDAI assessment of the patient’s response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment

**Authority required**

*Initial 2*

Change or re-commencement of treatment of Crohn disease in a patient assessed by CDAI.

Initial PBS-subsidised treatment with infliximab by a gastroenterologist or a consultant physician as specified in the NOTE below of a patient who:

(a) has a documented history of severe refractory Crohn disease; and
(b) in this treatment cycle, has received prior PBS-subsidised treatment with infliximab or adalimumab for this condition; and
(c) has not failed PBS-subsidised therapy with infliximab for this condition more than once in the current treatment cycle.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of TNF-alfa antagonist therapy within the timeframes specified in the relevant restriction.

Where the most recent course of PBS-subsidised TNF-alfa antagonist treatment was approved under an initial treatment restriction, the patient must have been assessed for response to that course following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

If the response assessment to the previous course of TNF-alfa antagonist treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of TNF-alfa antagonist.

Authority applications must be made in writing and must include:

(a) a completed authority prescription form; and
(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) the completed current Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient’s condition; and
where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to
and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for
Patients are eligible to receive continuing infliximab treatment in courses of up to 24 weeks providing they continue to sustain the response.
At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient,
have failed to sustain a response, to treatment with infliximab.

An adequate response to infliximab treatment is defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150.

**Authority required**

Continuing treatment of Crohn disease in a patient assessed by CDAI.

Continuing PBS-subsidised treatment with infliximab by a gastroenterologist, a consultant physician as specified in the NOTE below or other
consultant physician in consultation with a gastroenterologist, of a patient who:
(a) has a documented history of severe refractory Crohn disease; and
(b) has demonstrated or sustained an adequate response to treatment with infliximab.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or
consultant physicians [general medicine specialising in gastroenterology (code 82)].

An adequate response to infliximab treatment is defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150.
Applications for authorisation must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website
(www.medicareaustralia.gov.au)] which includes the following:
(i) the completed Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient’s condition.
The CDAI assessment must be no more than 1 month old at the time of application.
If the application is the first application for continuing treatment with infliximab, a CDAI assessment of the patient’s response must be made up to
12 weeks after the first dose so that there is adequate time for a response to be demonstrated.
The assessment of the patient’s response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course
and posted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure
continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment.

**Initial 1**

Initial treatment of Crohn disease in a patient with short gut syndrome or an ostomy patient.

Initial PBS-subsidised treatment with infliximab by a gastroenterologist, or consultant physician as specified in the NOTE below of a patient who
satisfies the following criteria:
(a) has confirmed Crohn disease defined by standard clinical, endoscopic and/or imaging features, including histological evidence with the diagnosis
confirmed by a gastroenterologist or consultant physician as specified in the NOTE below; and
(b) has diagnostic imaging or surgical evidence of short gut syndrome or has an ileostomy or colostomy; and
(c) has evidence of intestinal inflammation; and
(d) has signed a patient acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not
meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and
(e) has failed to achieve an adequate response to prior systemic drug therapy including:
(i) a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period; and
(ii) immunosuppressive therapy including:
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HIGHERLY SPECIFIED DRUGS PROGRAM (Private Hospital)

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>Qty $</th>
<th>Brand Name and Manufacturer</th>
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- azathioprine at a dose of at least 2 mg per kg daily for 3 or more months; or
- 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months; or
- methotrexate at a dose of at least 15 mg weekly for 3 or more months.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of the accepted toxicities including severity can be found on the Medicare Australia website [www.medicareaustralia.gov.au].

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the application:

(a) have evidence of intestinal inflammation, including:

(i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; AND/OR

(ii) faeces: higher than normal lactoferrin or calprotectin level; AND/OR

(iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery;

AND/OR

(b) be assessed clinically as being in a high faecal output state;

AND/OR

(c) be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of infliximab.

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the continuing treatment restriction. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website [www.medicareaustralia.gov.au] which includes the following:

(i) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and

(ii) reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; and

(iii) date of the most recent clinical assessment; and

(iv) the signed patient acknowledgement.

All assessments, pathology tests and diagnostic imaging studies must be made within 1 month of the date of application.

A maximum quantity and number of repeats to provide for an initial course of infliximab consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of infliximab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

The assessment of the patient’s response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment.

**Authority required**

Initial 2

Change or re-commencement of treatment of Crohn disease in a patient with short gut syndrome, an ostomy patient or a patient with extensive small intestine disease.

Initial PBS-subsidised treatment with infliximab by a gastroenterologist or a consultant physician as specified in the NOTE below of a patient who:

(a) has a documented history of severe refractory Crohn disease; and

(b) in this treatment cycle, has received prior PBS-subsidised treatment with infliximab or adalimumab for this condition; and
To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of TNF-alfa antagonist therapy within the timeframes specified in the relevant restriction.

Where the most recent course of PBS-subsidised TNF-alfa antagonist treatment was approved under an initial treatment restriction, the patient must have been assessed for response to that course following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

If the response assessment to the previous course of TNF-alfa antagonist treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of TNF-alfa antagonist.

Authority applications must be made in writing and must include:

- a completed authority prescription form; and
- a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
  - (i) reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criteria, if relevant; and
  - (ii) details of prior TNF alfa antagonist treatment including details of date and duration of treatment.

A maximum quantity and number of repeats to provide for an initial course of infliximab consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

The assessment of the patient’s response to this initial course of treatment must be made following a minimum of 12 weeks of therapy so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment.

**Authority required**

Continuing treatment of Crohn disease in a patient with short gut syndrome or an ostomy patient.

Continuing PBS-subsidised treatment with infliximab by a gastroenterologist, a consultant physician as specified in the NOTE below or other consultant physician in consultation with a gastroenterologist, of a patient who:

- has a documented history of severe refractory Crohn disease with intestinal inflammation and with short gut syndrome or with an ileostomy or colostomy; and
- has demonstrated or sustained an adequate response to treatment with infliximab.

**NOTE:** Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

An adequate response to infliximab treatment is defined as:

- improvement of intestinal inflammation as demonstrated by:
  - (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; AND/OR
  - (ii) faeces: normalisation of lactoferrin or calprotectin level; AND/OR
  - (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or
- reversal of high faecal output state; or
- avoidance of the need for surgery or total parenteral nutrition (TPN).

Applications for authorisation must be made in writing and must include:

- a completed authority prescription; and
- a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
  - (i) the reports and dates of the pathology or diagnostic imaging test(s) used to assess response to therapy or the date of clinical assessment.

The patient’s assessment must be no more than 1 month old at the time of application.

If the application is the first application for continuing treatment with infliximab, an assessment of the patient’s response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

The assessment of the patient’s response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for Crohn disease in a patient with short gut syndrome or an ostomy patient.

**NOTE:** Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].
those patients who meet the continuation criterion.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with infliximab.

Patients are eligible to receive continuing infliximab treatment in courses of up to 24 weeks providing they continue to sustain the response.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised. No applications for increased repeats will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday)

**Authority required**

**Initial 1**

Initial treatment of Crohn disease in a patient with extensive small intestine disease.

Initial PBS-subsidised treatment with infliximab by a gastroenterologist or a consultant physician as specified in the NOTE below, of a patient with severe refractory Crohn disease who satisfies the following criteria:

(a) has confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or consultant physician as specified in the NOTE below; and

(b) has extensive small intestinal disease with radiological evidence of intestinal inflammation affecting more than 50 cm of the small intestine; and

(c) has signed a patient acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and

(d) has failed to achieve an adequate response to prior systemic therapy including:

(i) a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period; and

(ii) immunosuppressive therapy including:

— azathioprine at a dose of at least 2 mg per kg daily for 3 or more months; or

— mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months; or

— methotrexate at a dose of at least 15 mg weekly for 3 or more months.

NOTE: Prescribers must be gastroenterologists [code 87], consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of the accepted toxicities including severity can be found on the Medicare Australia website [www.medicareaustralia.gov.au].

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the application:

(a) have severity of disease activity which results in a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220;

AND/OR

(b) have evidence of active intestinal inflammation, including:

(i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; AND/OR

(ii) faeces: higher than normal lactoferrin or calprotectin level; AND/OR

(iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery;

AND/OR

(c) be assessed clinically as being in a high faecal output state;

AND/OR

(d) be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of infliximab.

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the continuing treatment restriction. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website [www.medicareaustralia.gov.au]] which includes the following:
Continuing PBS-subsidised treatment with infliximab by a gastroenterologist, or consultant physician as specified in the NOTE below or other consultant physician in consultation with a gastroenterologist, of a patient who:

(a) has a documented history of severe refractory Crohn disease with extensive intestinal inflammation affecting more than 50 cm of the small intestine; and

(b) has demonstrated or sustained an adequate response to treatment with infliximab.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

An adequate response to infliximab treatment is defined as:

(a) a reduction in Crohn Disease Activity Index (CDAI) Score to no greater than 150; or

(b) improvement of intestinal inflammation as demonstrated by:

(i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; AND/OR

(ii) faeces: normalisation of lactoferrin or calprotectin level; AND/OR

(iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or

(c) reversal of high faecal output state; or

(d) avoidance of the need for surgery or total parenteral nutrition (TPN).

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) the completed Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient’s condition; or

(ii) the reports and dates of the pathology test or diagnostic imaging test(s) used to assess response to therapy; or

(iii) the date of clinical assessment.

All assessments must be no more than 1 month old at the time of application.

If the application is the first application for continuing treatment with infliximab, an assessment of the patient’s response must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

The assessment of the patient’s response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with infliximab.

Patients are eligible to receive continuing infliximab treatment in courses of up to 24 weeks providing they continue to sustain the response.
Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Initial 3 (grandfather)

Initial PBS-subsidised treatment of Crohn disease in a patient assessed by CDAI who has previously received non-PBS-subsidised therapy with infliximab.

Initial PBS-subsidised supply for continuing treatment with infliximab by a gastroenterologist, a consultant physician as specified in the NOTE below, or other consultant physician in consultation with a gastroenterologist of a patient who:

(a) has a documented history of severe refractory Crohn disease and was receiving treatment with infliximab prior to 7 March 2007; and
(b) had a Crohn Disease Activity Index (CDAI) Score of greater than or equal to 300 prior to commencing treatment with infliximab. Where a baseline CDAI assessment is not available, please call Medicare Australia on 1800 700 270 to discuss; and
(c) has signed a patient acknowledgement indicating that they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and
(d) has demonstrated or sustained an adequate response to treatment with infliximab. For advice please contact Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

An adequate response to infliximab treatment is defined as a reduction in Crohn Disease Activity Index (CDAI) Score to no greater than 150.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and
(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) the completed current and baseline Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient’s condition; and
(ii) the signed patient acknowledgement.

The current CDAI assessment must be no more than 1 month old at the time of application. The baseline CDAI assessment must be from immediately prior to commencing treatment with infliximab.

The assessment of the patient’s response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with infliximab.

Patients are eligible to receive continuing infliximab treatment in courses of up to 24 weeks providing they continue to sustain the response.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised. No applications for increased repeats will be authorised.

Where fewer than 2 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Patients may qualify for PBS-subsidised treatment under this restriction once only

Authority required

Initial 3

Initial PBS-subsidised treatment of Crohn disease in a patient with short gut syndrome, an ostomy patient, or a patient with extensive small intestine disease, who has previously received non-PBS-subsidised therapy with infliximab.

Initial PBS-subsidised supply for continuing treatment with infliximab by a gastroenterologist, a consultant physician as specified in the NOTE below, or other consultant physician in consultation with a gastroenterologist of a patient who:

(a) has a documented history of severe refractory Crohn disease and was receiving treatment with infliximab prior to 7 March 2007; and
(b) (1) has a history of extensive small intestinal disease with radiological evidence of intestinal inflammation affecting more than 50 cm of the small intestine; or
(2) has diagnostic imaging or surgical evidence of short gut syndrome or has an ileostomy or colostomy with a documented history of intestinal inflammation; and
(c) has signed a patient acknowledgement indicating that they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and
(d) has demonstrated or sustained an adequate response to treatment with infliximab according to the criteria included in the relevant continuation restriction. For advice please contact Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or...
consultant physicians (general medicine specialising in gastroenterology (code 82)).

The same criteria used to determine an inadequate response to prior treatment at baseline must be used to determine response to treatment and eligibility for continuing therapy, according to the criteria included in the continuing treatment restriction.

An adequate response to infliximab treatment is defined as:

(a) a reduction in Crohn Disease Activity Index (CDAI) score to no greater than 150; or

(b) improvement of intestinal inflammation as demonstrated by:

(i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; AND/OR

(ii) faeces: normalisation of lactoferrin or calprotectin level; AND/OR

(iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or

(c) reversal of high faecal output state; or

(d) avoidance of the need for surgery or total parenteral nutrition (TPN).

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) (1) the completed current and baseline Crohn Disease Activity Index (CDAI) Score calculation sheet, where relevant, including the date of the assessment of the patient’s condition; or

(ii) the reports and dates of the current and baseline pathology or diagnostic imaging test(s) in order to assess response to therapy; or

(iii) the signed patient acknowledgement.

The patient’s assessment must be no more than 1 month old at the time of application. The baseline CDAI assessments must be from immediately prior to commencing treatment with infliximab. Where a baseline assessment is not available, please call Medicare Australia on 1800 700 270 to discuss.

The assessment of the patient’s response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with infliximab.

Patients are eligible to receive continuing infliximab treatment in courses of up to 24 weeks providing they continue to sustain the response.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised. No applications for increased repeats will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Patients may qualify for PBS-subsidised treatment under this restriction once only

Note

Any queries concerning the arrangements to prescribe infliximab may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe infliximab should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Note

TREATMENT OF ADULT PATIENTS WITH SEVERE REFRACTORY CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab and infliximab for adult patients with severe refractory Crohn disease. Where the term ‘tumour necrosis factor (TNF) alfa antagonist’ appears in the following NOTES and restrictions, it refers to adalimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 2 TNF-alfa antagonists at any 1 time.

From 1 August 2008, under the PBS, all patients will be able to commence a treatment cycle where they may trial each PBS-subsidised TNF-alfa antagonist without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a TNF-alfa antagonist while they continue to show a response
A patient who received PBS-subsidised TNF-alfa antagonist treatment prior to 1 August 2008 is considered to be in their first cycle as of 1 August 2008.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised TNF-alfa antagonist more than twice.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised TNF-alfa antagonist therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised TNF-alfa antagonist treatment in the most recent cycle to the date of the first application for initial treatment with a TNF-alfa antagonist under the new treatment cycle.

A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised TNF-alfa antagonist therapy after 1 August 2008.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised TNF-alfa antagonist treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) TNF-alfa antagonist therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to re-commence treatment with a specific TNF-alfa antagonist following a break in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks of therapy for infliximab.

From 1 August 2008, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

For second and subsequent courses of PBS-subsidised TNF-alfa antagonist treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Adalimumab only: Two completed authority prescriptions must be submitted with every initial application for adalimumab. One prescription must be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats. The second prescription must be written for 2 doses of 40 mg and 2 repeats.

(b) Continuing treatment. Following the completion of an initial treatment course with a specific TNF-alfa antagonist, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing TNF-alfa antagonist treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted TNF-alfa antagonist supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised TNF-alfa antagonist is approved, a patient may swap if eligible to the alternate TNF-alfa antagonist within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Crohn Disease Activity Index (CDAI) Score, evidence of intestinal inflammation), or the prior corticosteroid therapy and immunosuppressive therapy.

A patient may trial the alternate TNF-alfa antagonist at any time, regardless of whether they are receiving therapy (initial or continuing) with a TNF-alfa antagonist at the time of the application. However, they cannot swap to a particular TNF-alfa antagonist if they have failed to respond to prior treatment with that drug two times within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to the alternate TNF-alfa antagonist should be accompanied by the approved authority prescription or remaining repeats for the TNF-alfa antagonist the patient is ceasing.

(3) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the CDAI or evidence of intestinal inflammation submitted with the first authority application for a TNF-alfa antagonist. However, prescribers may provide new
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised TNF-alfa antagonist therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with a corticosteroid and at least 1 immunosuppressive agent, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the CDAI score or the indices of intestinal inflammation are measured.

(5) Patients ‘grandfathered’ onto PBS-subsidised treatment with adalimumab or infliximab.

A patient who commenced treatment with adalimumab for severe refractory Crohn disease prior to 9 November 2007 or infliximab prior to 7 March 2007 and who continues to receive treatment at the time of application, may qualify for treatment under the initial ‘grandfather’ treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with adalimumab or infliximab will be authorised under this criterion.

Following completion of the initial PBS-subsidised course, further applications for treatment with adalimumab or infliximab will be assessed under the continuing treatment restriction.

‘Grandfather’ arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a ‘grandfather’ patient must requalify for initial treatment under the criteria that apply to a new patient. See ‘Re-commencement of treatment after a 5-year break in PBS-subsidised therapy’ above for further details.

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### Table: Highly Specialised Drugs Program (Private Hospital)

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### INFLEXIMAB

**Authority required**

Initial treatment [Initial 1, Whole body (New patients — No prior biological agent)]

Initial treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over who:

(a) have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis; and

(b) have not received any prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle; and

(c) have signed a patient and prescriber acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment (whole body); and

(d) have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 3 of the following 4 treatments:

(i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or

(ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; and/or

(iii) cyclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; and/or

(iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, please provide details of the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity to necessitate permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of acceptable toxicities including severity, associated with phototherapy, methotrexate, cyclosporin and acitretin, can be found on the Medicare Australia website (www.medicareaustralia.gov.au).

The following initiation criterion indicates failure to achieve an adequate response and must be demonstrated in all patients at the time of the application:

(a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 1 month old at the time of application.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient’s condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; and

(iii) the signed patient and prescriber acknowledgements.
A maximum of 22 weeks of treatment with infliximab will be authorised under this restriction.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 22 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period beyond 22 weeks.

A PASI assessment of the patient’s response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment

**Authority required**

Initial or re-Treatment (Initial 2, Whole body [Received prior biological agent under PBS])

Treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over who:

(a) have a documented history of severe chronic plaque psoriasis; and

(b) have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle; and

(c) have not failed PBS-subsidised therapy with infliximab for the treatment of this condition in the current Treatment Cycle.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient’s condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and

(ii) details of prior biological treatment, including dosage, date and duration of treatment.

Applications for patients who have demonstrated a response to PBS-subsidised infliximab treatment within this Treatment Cycle and who wish to re-commence infliximab treatment within the same Cycle following a break in therapy, will only be approved where evidence of the patient’s response to their most recent course of PBS-subsidised infliximab treatment has been submitted to Medicare Australia within 1 month of cessation of treatment.

A maximum of 22 weeks of treatment with infliximab will be authorised under this restriction.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 22 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period beyond 22 weeks.

A PASI assessment of the patient’s response to this course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment

**Authority required**

Continuing treatment (Whole body)

Continuing PBS-subsidised treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over:

(a) who have a documented history of severe chronic plaque psoriasis; and

(b) whose most recent course of PBS-subsidised biological treatment for this condition in this Treatment Cycle was with infliximab; and

(c) who have demonstrated an adequate response to their most recent course of treatment with infliximab.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the pre-
biological treatment baseline value for this Treatment Cycle.

This assessment must be provided to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with infliximab, the assessment of response must be after a minimum of 12 weeks of treatment with an initial course.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and
(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
   (i) the completed Psoriasis Area and Severity Index (PASI) calculation sheet along with the date of the assessment of the patient’s condition.

The most recent PASI assessment must be no more than 1 month old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with infliximab.

A maximum of 24 weeks of treatment with infliximab will be authorised under this restriction.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for continuing authority applications, or for treatment that would otherwise extend the treatment period beyond 24 weeks.

A PASI assessment of the patient’s response must be conducted within 4 weeks prior to completion of this course of treatment. This assessment, which will be used to determine eligibility for further continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment.

Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may re-commence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle

**Authority required**

Initial treatment [Initial 1, Face, hand, foot (New patients — No prior biological agent)]

Initial treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over who:

(a) have severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis; and
(b) have not received any prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle; and
(c) have signed a patient and prescriber acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment (face, hand, foot); and
(d) have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 3 of the following 4 treatments:
   (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or
   (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; and/or
   (iii) cyclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; and/or
   (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity to necessitate permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of acceptable toxicities including severity, associated with phototherapy, methotrexate, cyclosporin and acitretin, can be found on the Medicare Australia website (www.medicareaustralia.gov.au).

The following initiation criterion indicates failure to achieve an adequate response and must be demonstrated in all patients at the time of the application:

(a) Chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:
   (i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment; or
   (ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.
(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.
Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient’s condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; and

(iii) the signed patient and prescriber acknowledgements.

A maximum of 22 weeks of treatment with infliximab will be authorised under this restriction.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 22 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period beyond 22 weeks.

A PASI assessment of the patient’s response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

**Authority required**

**Initial or re-Treatment [Initial 2, Face, hand, foot (Received prior biological agent under PBS)]**

Treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over who:

(a) have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot; and

(b) have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle; and

(c) have not failed PBS-subsidised therapy with infliximab for the treatment of this condition in the current Treatment Cycle.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient’s condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and

(ii) details of prior biological treatment, including dosage, date and duration of treatment.

Applications for patients who have demonstrated a response to PBS-subsidised infliximab treatment within this Treatment Cycle and who wish to re-commence infliximab treatment within the same Cycle following a break in therapy, will only be approved where evidence of the patient’s response to their most recent course of PBS-subsidised infliximab treatment has been submitted to Medicare Australia within 1 month of cessation of treatment.

A maximum of 22 weeks of treatment with infliximab will be authorised under this restriction.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 22 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period beyond 22 weeks.

A PASI assessment of the patient’s response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must
cease PBS-subsidised therapy. These patients may re-commence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

Authority required

Continuing PBS-subsidised treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over:

(a) who have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot; and
(b) whose most recent course of PBS-subsidised biological treatment for this condition in this Treatment Cycle was with infliximab; and
(c) who have demonstrated an adequate response to treatment with infliximab.

An adequate response to infliximab treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the pre-biological treatment baseline values; or
(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the pre-biological treatment baseline value.

This assessment must be provided to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with infliximab, the assessment of response must be after a minimum of 12 weeks of treatment with an initial course.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and
(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams along with the date of the assessment of the patient’s condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

The most recent PASI assessment must be no more than 1 month old at the time of application.

A maximum of 24 weeks of treatment with infliximab will be authorised under this restriction.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for continuing authority applications, or for treatment that would otherwise extend the treatment period beyond 24 weeks.

A PASI assessment of the patient’s response must be conducted within 4 weeks prior to completion of this course of treatment. This assessment, which will be used to determine eligibility for further continuing treatment must be submitted to Medicare Australia no later than 1 month from the date of completion of this course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment.

The PASI assessment for continuing treatment must be performed on the same affected area assessed at baseline.

Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may re-commence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

Note

Any queries concerning the arrangements to prescribe infliximab may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe infliximab should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

Note

TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, etanercept, infliximab and ustekinumab, for adult patients with severe chronic plaque psoriasis. Therefore, where the term ‘biological agents’ appears in the following NOTES and restrictions, it only refers to adalimumab, etanercept, infliximab and ustekinumab.

From 1 March 2010, all patients will be able to commence a ‘Biological Treatment Cycle’ (Cycle), where they may trial adalimumab, etanercept,
infliximab or ustekinumab without having to meet the initial treatment criteria, that is they will not need to experience a disease flare when swapping to an alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

A patient who received PBS-subsidised biological agent treatment for chronic plaque psoriasis prior to 1 March 2010 is considered to be in their first Cycle as of 1 March 2010.

Patients are eligible for PBS-subsidised treatment with only 1 biological agent at any 1 time. Within the same Treatment Cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for a PBS-subsidised biological agent, they must change to an alternate agent if they wish to continue PBS-subsidised biological treatment. A patient who, prior to 1 March 2010, was authorised to receive PBS-subsidised initial treatment for chronic plaque psoriasis with the same agent twice, is exempt from this condition in respect of applications approved prior to 1 March 2010.

Patients must be assessed for response to each course of continuing treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a Treatment Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological agent therapy before they are eligible to commence the next Cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological agent treatment in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Treatment Cycle.

Patients for whom a break in PBS-subsidised therapy of less than 5 years duration has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle.

There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe chronic plaque psoriasis after 1 March 2010.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Application for approval for initial treatment.

Applications for a course of initial treatment should be made in the following situations:

(i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy; or

(ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under ‘(4) Swapping therapy’ below]; or

(iii) patients who wish to re-commence treatment following a break in PBS-subsidised therapy with that agent (Initial 2).

All applications for initial treatment will be limited to provide for a maximum of 16 weeks of treatment in the case of adalimumab and etanercept, 22 weeks of treatment in the case of infliximab and 28 weeks of treatment in the case of ustekinumab.

(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological agent, a PASI assessment must be conducted at least 12 weeks of treatment. This assessment must be submitted to Medicare Australia within 1 month of the completion of this initial treatment course. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

(3) Application for continuing treatment.

Following the completion of an initial treatment course of a biological agent to which an adequate response has been demonstrated, patients may qualify to receive up to 24 weeks of continuing treatment with that biological agent. Patients are eligible to continue to receive continuous treatment with 24 week courses providing they continue to sustain a response.

For second and subsequent courses of PBS-subsidised treatment with adalimumab, etanercept, infliximab or ustekinumab it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Where a response assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to sustain a response to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

(4) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate agent within the same Treatment Cycle without having to requalify with respect to disease severity (i.e. a PASI score of greater than 15), or prior treatment requirements.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

Patients may trial an alternate biological agent at any time, regardless of whether they are receiving therapy with a biological agent at the time of the application or not. However, they cannot swap to a particular agent if they have failed to respond to treatment with that particular agent within the same Cycle.

Patients who commenced treatment with adalimumab prior to 1 June 2009 or ustekinumab prior to 1 March 2010 access these interchangeability...
arrangements in the same way as patients who have not.

To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the agent being ceased.

(5) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment authority is submitted within a Treatment Cycle and subsequent response will be assessed according to this revised PASI score.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatment applications.

(6) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

Patients who wish to trial a second or subsequent Biological Treatment Cycle, following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment according to the criteria of the relevant restriction and index of disease severity. Patients must have had at least 1 prior treatment, as listed in the criteria, for a minimum of 6 weeks, and must have a PASI assessment conducted preferably whilst still on treatment, but no later than 1 month following cessation of treatment. The PASI assessment must be no older than 1 month at the time of application.

Note
No applications for increased repeats will be authorised.

9617E infliximab 100 mg injection, 1 x 100 mg vial 1 .. .. 788.53 Remicade JC

INFLIXIMAB
Authority required
Initial 1

Initial treatment of complex refractory FISTULISING CROHN DISEASE.

Initial PBS-subsidised treatment with infliximab by a gastroenterologist or a consultant physician as specified in the NOTE below, of a patient with complex refractory fistulising Crohn disease who:

(a) has confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician as specified in the NOTE below; and

(b) has an externally draining enterocutaneous or rectovaginal fistula; and

(c) has signed a patient acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criteria for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

Authority applications must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Fistulising Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) a completed current Fistula Assessment Form including the date of assessment of the patient’s condition; and

(ii) a signed patient acknowledgement.

The most recent fistula assessment must be no more than 1 month old at the time of application.

A maximum quantity and number of repeats to provide for an initial course of infliximab consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6 will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete 3 doses of infliximab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

An assessment of the patient’s response to this initial course of treatment must be made up to 12 weeks after the first dose (up to 6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

This assessment must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment

Authority required
Initial 2

Change or re-commencement of treatment of complex refractory FISTULISING CROHN DISEASE.

Initial PBS-subsidised treatment with infliximab of complex refractory fistulising Crohn disease by a gastroenterologist or a consultant physician as
specified in the NOTE below, of a patient with complex refractory fistulising Crohn disease who:

(a) has a documented history of complex refractory fistulising Crohn disease; and

(b) in this treatment cycle, has received prior PBS-subsidised treatment with adalimumab or infliximab for a draining enterocutaneous or rectovaginal fistula; and

(c) has not failed PBS-subsidised therapy with infliximab for this condition more than once in the current treatment cycle.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of TNF-alfa antagonist therapy within the timeframes specified in the relevant restriction.

Where the most recent course of PBS-subsidised TNF-alfa antagonist treatment was approved under an initial treatment restriction, the patient must have been assessed for response to that course following a minimum of 12 weeks therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

If the response assessment to the previous course of TNF-alfa antagonist treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of TNF-alfa antagonist.

Authority applications must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Fistulising Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) a completed current Fistula Assessment Form including the date of assessment of the patient’s condition; and
(ii) details of prior TNF-alfa antagonist treatment including details of date and duration of treatment.

The most recent fistula assessment must be no more than 1 month old at the time of application.

A maximum quantity and number of repeats to provide for an initial course of infliximab consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete 3 doses of infliximab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

An assessment of the patient’s response to this initial course of treatment must be made up to 12 weeks after the first dose (up to 6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

This assessment must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment.

**Authority required**

Initial 3 (grandfather)

Initial PBS-subsidised treatment of complex refractory FISTULISING CROHN DISEASE in a patient who has previously received non-PBS-subsidised therapy with infliximab.

Initial PBS-subsidised supply for continuing treatment with infliximab by a gastroenterologist, a consultant physician as specified in the NOTE below, or other consultant physician in consultation with a gastroenterologist of a patient who satisfies the following criteria:

(a) has a documented history of complex refractory fistulising Crohn disease and was receiving treatment with infliximab prior to 1 March 2010; and

(b) had a draining enterocutaneous or rectovaginal fistula(e) prior to commencing treatment with infliximab; and

(c) has signed a patient acknowledgement indicating that they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criteria for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and

(d) is receiving treatment with infliximab at the time of application; and

(e) has demonstrated or sustained an adequate response to treatment with infliximab.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

An adequate response to infliximab treatment is defined as:

(a) a decrease from baseline in the number of open draining fistulae of greater than or equal to 50%; and/or

(b) a marked reduction in drainage of all fistula(e) from baseline, together with less pain and induration as reported by the patient.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Fistulising Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) a completed current and baseline Fistula Assessment form including the date of assessment of the patient's condition; and
The current fistula assessment must be no more than 1 month old at the time of application.

The baseline fistula assessment must be from immediately prior to commencing treatment with infliximab.

An assessment of the patient’s response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criteria.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with infliximab.

Patients are eligible to receive continuing infliximab treatment in courses of up to 24 weeks providing they continue to sustain the response.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised. No applications for increased repeats will be authorised.

Where fewer than 2 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Patients may qualify for PBS-subsidised treatment under this restriction once only

**Authority required**

Continuing treatment of complex refractory FISTULISING CROHN DISEASE.

Continuing PBS-subsidised treatment with infliximab by a gastroenterologist, a consultant physician as specified in the NOTE below or other consultant physician in consultation with a gastroenterologist, of a patient who:

(a) has a documented history of complex refractory fistulising Crohn disease; and

(b) has demonstrated or sustained an adequate response to treatment with infliximab.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

An adequate response is defined as:

(a) a decrease from baseline in the number of open draining fistulae of greater than or equal to 50%; and/or

(b) a marked reduction in drainage of all fistula(e) from baseline, together with less pain and induration as reported by the patient.

Authority applications must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Fistulising Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes a completed Fistula Assessment form including the date of the assessment of the patient's condition.

The fistula assessment must be no more than 1 month old at the time of application.

If the application is the first application for continuing treatment with infliximab, an assessment of the patient’s response must be made up to 12 weeks after the first dose so that there is adequate time for a response to be demonstrated.

An assessment of the patient’s response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criteria.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with infliximab.

Patients are eligible to receive continuing infliximab treatment in courses of up to 24 weeks providing they continue to sustain the response.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised. No applications for increased repeats will be authorised.

Where fewer than 2 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday)

**Note**

Any queries concerning the arrangements to prescribe infliximab may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe infliximab should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001
A patient is eligible for PBS-subsidised treatment with only 1 of the 2 TNF-alfa antagonists at any 1 time.

From 1 April 2011, under the PBS, all patients will be able to commence a treatment cycle where they may trial each PBS-subsidised TNF-alfa antagonist without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a TNF-alfa antagonist while they continue to show a response to therapy.

A patient who received PBS-subsidised TNF-alfa antagonist treatment prior to 1 April 2011 is considered to be in their first cycle as of 1 April 2011. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised TNF-alfa antagonist more than twice.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised TNF-alfa antagonist therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised TNF-alfa antagonist treatment in the most recent cycle to the date of the first application for initial treatment with a TNF-alfa antagonist under the new treatment cycle.

A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised TNF-alfa antagonist therapy after 1 April 2011.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised TNF-alfa antagonist treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) TNF-alfa antagonist therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or

(iii) a patient wishes to re-commence treatment with a specific TNF-alfa antagonist following a break in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks of therapy for infliximab.

From 1 April 2011, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

For second and subsequent courses of PBS-subsidised TNF-alfa antagonist treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Adalimumab only: Two completed authority prescriptions must be submitted with every initial application for adalimumab. One prescription must be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats. The second prescription must be written for 2 doses of 40 mg and 2 repeats.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific TNF-alfa antagonist, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing TNF-alfa antagonist treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted TNF-alfa antagonist supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised TNF-alfa antagonist is approved, a patient may swap if eligible to the alternate TNF-alfa antagonist within the same treatment cycle.

A patient may trial the alternate TNF-alfa antagonist at any time, regardless of whether they are receiving therapy (initial or continuing) with a TNF-alfa antagonist at the time of the application. However, they cannot swap to a particular TNF-alfa antagonist if they have failed to respond to prior
Interleukin inhibitors

**TOCILIZUMAB**

**Authority required**

Severe active juvenile idiopathic arthritis

**Clinical criteria:**

Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years, AND

Patient must have received no PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition in the previous 24 months; OR

Patient must have received no PBS-subsidised bDMARD treatment for at least 5 years if they failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) in their last treatment cycle, AND

Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR

Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR

Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above, must include at least 3 months continuous treatment with each of at least 2 DMARDs, with one or more of the following DMARDs being used in place of the DMARDs which are contraindicated or not tolerated: (i) azathioprine at a dose of at least 1 mg/kg per day; and/or (ii) cyclosporin at a dose of at least 2 mg/kg/day; and/or (iii) sodium aurothiomalate at a dose of 50 mg weekly, AND

Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

Patient must be aged 18 years or older.
Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

For the purposes of this restriction ‘biological disease modifying anti-rheumatic drug’ and ‘bDMARD’ mean adalimumab, etanercept or tocilizumab.

If methotrexate is contraindicated according to the TGA-approved Product Information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance and dose for each DMARD must be provided in the authority application.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

(a) an active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(1) completed authority prescription form(s); and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form; and

(3) a signed patient acknowledgement.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

If a patient fails to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle. A patient may re-trial tocilizumab after a minimum of 5 years have elapsed between the date of the last approval for PBS-subsidised bDMARD therapy in the last treatment cycle and the date of the first application under a new treatment cycle.

Note

The Department of Human Services website (www.humanservices.gov.au) has details of the toxicities, including severity, which will be accepted for the following purposes:
(a) exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose;

(b) substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial;

(c) exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy.

Note
Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs

Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Note
TREATMENT OF ADULT PATIENTS WITH A HISTORY OF JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient over 18 years who has a history of juvenile idiopathic arthritis with onset prior to the age of 18 years. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.

From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and
(ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 5 year break in PBS-subsidised bDMARD therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date of the last approval for PBS-subsidised bDMARD therapy in the last treatment cycle to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 24 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 24 months may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 24 months must commence a new treatment cycle. The length of the break in therapy is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing
their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

A patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count and ESR/CRP) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.

(4) Re-commencement of treatment after a 24 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 24 months, must requalify for treatment under the Initial 1 treatment restriction.

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after break of less than 24 months)

Clinical criteria:

Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years,

AND

Patient must have received prior PBS-subsidised treatment with adalimumab, etanercept or tocilizumab for this condition in this treatment cycle,

AND

Patient must not have failed PBS-subsidised therapy with tocilizumab for this condition in the current treatment cycle,

AND

Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

For the purposes of this restriction ‘biological disease modifying anti-rheumatic drug’ and ‘bDMARD’ mean adalimumab, etanercept or tocilizumab.

The authority application must be made in writing and must include:

(1) completed authority prescription form(s); and
At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

Applications for a patient who has received PBS-subsidised treatment with tocilizumab in this treatment cycle and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient’s most recent course of PBS-subsidised tocilizumab treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised tocilizumab treatment was approved under either of the Initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised tocilizumab treatment was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to tocilizumab.

If a patient fails to respond to PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) an active joint count of fewer than 10 active (swollen and tender) joints; or

(b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or

(c) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

Note

TREATMENT OF ADULT PATIENTS WITH A HISTORY OF JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient over 18 years who has a history of juvenile idiopathic arthritis with onset prior to the age of 18 years. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.

From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 5 year break in PBS-subsidised bDMARD therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date of the last approval for PBS-subsidised bDMARD therapy in the last treatment cycle to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 24 months immediately prior to making a new application, on or after 1 April
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

There is no limit to the number of treatment cycles a patient may undertake.

How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

A patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count and ESR/CRP) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.

Re-commencement of treatment after a 24 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 24 months, must requalify for treatment under the Initial 1 treatment restriction.

**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months) or Initial 2 (change or recommencement of treatment after break of less than 24 months) – balance of supply.
Clinical criteria:
Patient must have received insufficient tocilizumab therapy under the Initial 1 (new patient or patient recommencing treatment after break of more than 24 months) restriction to complete 16 weeks treatment; OR

Patient must have received insufficient tocilizumab therapy under the Initial 2 (change or recommencement of treatment after break of less than 24 months) restriction to complete 16 weeks treatment,

AND

The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Treatment criteria:
Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Note
Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
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Authority required
Severe active juvenile idiopathic arthritis
Treatment Phase: Continuing treatment

Clinical criteria:
Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years,

AND

Patient must have demonstrated an adequate response to treatment with tocilizumab,

AND

Patient must have received tocilizumab as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment in this treatment cycle,

AND

Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

Population criteria:
Patient must be aged 18 years or older.

Treatment criteria:
Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

For the purposes of this restriction ‘biological disease modifying anti-rheumatic drug’ and ‘bDMARD’ mean adalimumab, etanercept or tocilizumab.

An adequate response to treatment is defined as:
an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND
either of the following:
(a) an active joint count of fewer than 10 active (swollen and tender) joints; or
(b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or
(c) a reduction in the number of the following active joints, from at least 4, by at least 50%:
(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.
The authority application must be made in writing and must include:

(1) completed authority prescription form(s); and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 5 repeats will be authorised.

All applications for continuing treatment with tocilizumab must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with tocilizumab, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab.

If a patient fails to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle.

**Note**

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

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Prior Written Approval of Complex Drugs
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**Note**

TREATMENT OF ADULT PATIENTS WITH A HISTORY OF JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient over 18 years who has a history of juvenile idiopathic arthritis with onset prior to the age of 18 years. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.

From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 5 year break in PBS-subsidised bDMARD therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date of the last approval for PBS-subsidised bDMARD therapy in the last treatment cycle to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 24 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 24 months may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 24 months must commence a new treatment cycle. The length of the break in therapy is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake.
(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that bDMARD (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

A patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count and ESR/CRP) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.

(4) Re-commencement of treatment after a 24 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 24 months, must requalify for treatment under the Initial 1 treatment restriction.

**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing Treatment – balance of supply

**Clinical criteria:**

Patient must have received insufficient tocilizumab therapy under the Continuing Treatment restriction to complete 24 weeks treatment, AND

The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Treatment criteria:**

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.
Note

Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:
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HOBART TAS 7001

TOCILIZUMAB
Authority required
Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 12 months)

Clinical criteria:
Patient must have severe active juvenile idiopathic arthritis,

AND
Patient must have received no prior PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition; OR
Patient must not have received PBS-subsidised treatment with adalimumab, etanercept or tocilizumab for this condition in the previous 12 months,

AND
Patient must have demonstrated severe intolerance of, or toxicity due to, methotrexate; OR
Patient must have demonstrated failure to achieve an adequate response to 1 or more of the following treatment regimens: (i) oral or parenteral methotrexate at a dose of at least 20 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; or (ii) oral methotrexate at a dose of at least 10 mg per square metre weekly together with at least 1 other disease modifying drug (DMARD), alone or in combination with corticosteroids, for a minimum of 3 months,

AND
Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:
Patient must be under 18 years of age and a parent or authorised guardian must have signed a patient acknowledgement.

Treatment criteria:
Must be treated by a paediatric rheumatologist; OR
Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.

Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.

Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis.

If treatment with methotrexate alone or in combination with another DMARD is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details
The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

(a) an active joint count of at least 20 active (swollen and tender) joints; OR
(b) at least 4 active joints from the following list:
   (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
   (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count assessment must be performed preferably whilst still on DMARD treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

The authority application must be made in writing and must include:

(1) completed authority prescription form(s); and
(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form; and
(3) an acknowledgement signed by a parent or authorised guardian.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

If a patient fails to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle. A patient may re-trial tocilizumab after a minimum of 12 months have elapsed between the date the last PBS-subsidised bDMARD was stopped and the date of the first application under a new treatment cycle.

TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient who has severe active juvenile idiopathic arthritis. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.

From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and
(ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised biological therapy before they are eligible to receive further

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Note

Use of alternative DMARDs in children is dependent on approval by the Therapeutic Goods Administration as age restrictions may apply.

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (Including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

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Note

TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient who has severe active juvenile idiopathic arthritis. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.

From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and
(ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised biological therapy before they are eligible to receive further
A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 12 months immediately prior to making a new application, or on or after 1 April 2014, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 12 months may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 12 months (Initial 1); or

(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or

(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 12 months in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 12 months.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.

(4) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 12 months, must requalify for treatment under the Initial 1 treatment restriction.

(5) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with bDMARDs should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to the Department of Human Services at the time treatment is ceased.
Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after break of less than 12 months)

Clinical criteria:

- Patient must have a documented history of severe active juvenile idiopathic arthritis, AND
- Patient must have received prior PBS-subsidised treatment with adalimumab, etanercept or tocilizumab for this condition in this treatment cycle, AND
- Patient must not have failed PBS-subsidised therapy with tocilizumab for this condition in the current treatment cycle, AND
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be under 18 years of age.

Treatment criteria:

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.

The authority application must be made in writing and must include:

1. completed authority prescription form(s); and
2. a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

Applications for a patient who has received PBS-subsidised treatment with tocilizumab in this treatment cycle and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised tocilizumab treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised tocilizumab treatment was approved under either of the Initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised tocilizumab treatment was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab.

If a patient fails to respond to PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).
**TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient who has severe active juvenile idiopathic arthritis. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.

From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

*(i)* continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and

*(ii)* fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised biological therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 12 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 12 months may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake.

**(i)** How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.

(a) Initial treatment.

Applications for initial treatment should be made where:

*(i)* a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

*(ii)* a patient wishes to re-commence treatment with a PBS-subsidised bDMARD following a break in PBS-subsidised therapy of more than 12 months (Initial 1); or

*(iii)* a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or

*(iv)* a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 12 months in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD therapy.

### Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

### Note

**TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient who has severe active juvenile idiopathic arthritis. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.

From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

*(i)* continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and

*(ii)* fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised biological therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 12 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 12 months may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake.

**(i)** How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.

(a) Initial treatment.

Applications for initial treatment should be made where:

*(i)* a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

*(ii)* a patient wishes to re-commence treatment with a PBS-subsidised bDMARD following a break in PBS-subsidised therapy of more than 12 months (Initial 1); or

*(iii)* a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or

*(iv)* a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 12 months in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD therapy.
Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 12 months.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.

(4) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 12 months, must requalify for treatment under the Initial 1 treatment restriction.

(5) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with bDMARDS should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to the Department of Human Services at the time treatment is ceased.

**Authority required**

Severe active juvenile idiopathic arthritis

**Treatment Phase:** Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 12 months) or Initial 2 (change or recommencement of treatment after break of less than 12 months) – balance of supply.

**Clinical criteria:**

Patient must have received insufficient tocilizumab therapy under the Initial 1 (new patient or patient recommencing treatment after break of more than 12 months) restriction to complete 16 weeks treatment; OR

Patient must have received insufficient tocilizumab therapy under the Initial 2 (change or recommencement of treatment after break of less than 12 months) restriction to complete 16 weeks treatment,

AND

The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Treatment criteria:**

Must be treated by a paediatric rheumatologist; OR

Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

**Note**

Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

**Authority required**

Severe active juvenile idiopathic arthritis

**Treatment Phase:** Continuing treatment

**Clinical criteria:**

Patient must have a documented history of severe active juvenile idiopathic arthritis,
Patient must have demonstrated an adequate response to treatment with tocilizumab, AND

Patient must have received tocilizumab as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment in this treatment cycle, AND

Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

Treatment criteria:
Must be treated by a rheumatologist; OR
Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.

An adequate response to treatment is defined as:
(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:
(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurement of joint count submitted with the initial treatment application.

The authority application must be made in writing and must include:
(1) completed authority prescription form(s); and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 5 repeats will be authorised.

All applications for continuing treatment with tocilizumab must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with tocilizumab, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab.

If a patient fails to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle.

**Note**
Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient who has severe active juvenile idiopathic arthritis. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.

From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and
(ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised biological therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 12 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 12 months may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 12 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 12 months in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 12 months.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.

(4) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 12 months, must requalify for treatment under the Initial 1 treatment restriction.

(5) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with bDMARDs should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to the Department of Human Services at the time treatment is ceased.

**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing Treatment – balance of supply

**Clinical criteria:**

Patient must have received insufficient tocilizumab therapy under the Continuing Treatment restriction to complete 24 weeks treatment, AND

The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Treatment criteria:**

Must be treated by a rheumatologist; OR

Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

**Note**

Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

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**TOCILIZUMAB**

**Authority required**

Initial 1 (new and recommencing patients after a break of more than 12 months)

Initial treatment by a rheumatologist, or under the supervision of a paediatric rheumatology treatment centre, of a patient under 18 years who:

(a) has been diagnosed with systemic juvenile idiopathic arthritis; AND

(b) has polyarticular course disease and either:

(i) failure to achieve an adequate response to the following treatment regimen (see (1) below for definition of failure to achieve an adequate response):

— oral or parenteral methotrexate at a dose of at least 15 mg per square metre weekly, alone or in combination with oral or intra-articular...
subsidised treatment was stopped and the date of the first application under a new treatment cycle. A patient may re-trial tocilizumab after a minimum of 12 months have elapsed between the date the last PBS-subsidised treatment was stopped and the date of the first application under a new treatment cycle. If a patient fails to respond to 2 courses of treatment in a treatment cycle they will not be eligible to receive further PBS-subsidised tocilizumab therapy in that treatment cycle. A patient may re-trial tocilizumab after a minimum of 12 months have elapsed between the date the last PBS-subsidised treatment was stopped and the date of the first application under a new treatment cycle.

Authority required
Initial 2 (retrial or recommencement of treatment after a break of less than 12 months)
An assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and

(c) has not failed PBS-subsidised therapy with tocilizumab for this condition more than once in the current treatment cycle.

The authority application must be made in writing and must include:

(1) completed authority prescription form(s); and

(2) a completed Systemic Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) pathology reports detailing CRP and platelet count where appropriate.

Applications for a patient who has received PBS-subsidised treatment with tocilizumab in this treatment cycle and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient’s most recent course of PBS-subsidised tocilizumab treatment, within the timeframes specified below.

A maximum of 16 weeks of treatment will be authorised under this restriction.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for two infusions (one month supply). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

Where fewer than 3 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with tocilizumab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

An assessment of the patient’s response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criteria. Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with tocilizumab.

Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to that course of tocilizumab.

If a patient fails to respond to 2 courses of treatment they will not be eligible to receive further PBS-subsidised tocilizumab therapy in this treatment cycle. A patient may re-trial tocilizumab after a minimum of 12 months have elapsed between the date the last PBS-subsidised treatment was stopped and the date of the first application under a new treatment cycle

Authority required

Initial 3 (‘grandfather’ patients)

Initial treatment by a rheumatologist, or under the supervision of a paediatric rheumatology treatment centre, of a patient who:

(a) has a documented history of systemic juvenile idiopathic arthritis; and

(b) was receiving treatment with tocilizumab prior 1 November 2011; and

(c) has demonstrated a response as specified in the criteria for continuing PBS-subsidised treatment with tocilizumab; and

(d) is receiving treatment with tocilizumab at the time of application.

To ensure consistency in determining response, the same indices of disease severity used to establish the baseline must be provided for all subsequent continuing treatment applications.

The authority application must be made in writing and must include:

(1) completed authority prescription form(s); and

(2) a completed Systemic Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) pathology reports detailing CRP and platelet count where appropriate; and

(3) a signed patient or authorised guardian acknowledgement form.

The most recent systemic juvenile idiopathic arthritis assessment must be no more than 1 month old at the time of application.

The baseline systemic juvenile idiopathic arthritis assessment must be provided and must be from immediately prior to commencing treatment with tocilizumab. (See NOTE (3) above for definition of baseline measurements to determine response.)

An assessment of the patient’s response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criteria.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with tocilizumab.

Patients are eligible to receive continuing tocilizumab treatment in courses of up to 24 weeks providing they continue to sustain the response.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for two infusions (one month supply). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 5 repeats will be authorised.

Where fewer than 5 repeats are initially requested with the authority prescription, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to
HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

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5 p.m. EST Monday to Friday).

A patient may only qualify for PBS-subsidised treatment under this restriction once

**Authority required**

Continuing treatment

Continuing treatment with tocilizumab, by a rheumatologist or under the supervision of a paediatric rheumatology treatment centre, of a patient who:

(a) has a documented history of systemic juvenile idiopathic arthritis; AND

(b) has demonstrated an adequate response to treatment with tocilizumab.

An adequate response to treatment is defined as:

(a) in a patient with polyarticular course disease:

(i) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(ii) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

— elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

— shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

(b) in a patient with refractory systemic symptoms:

(i) absence of fever greater than 38 degrees Celsius in the preceding seven days; AND/OR

(ii) a reduction in the CRP level and platelet count by at least 30% from baseline; AND/OR

(iii) a reduction in the dose of corticosteroid by at least 30% from baseline.

The authority application must be made in writing and must include:

(1) completed authority prescription form(s); and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) baseline and current pathology reports detailing CRP and platelet count where appropriate.

The most recent systemic juvenile idiopathic arthritis assessment must be no more than 1 month old at the time of application.

Where the most recent course of PBS-subsidised tocilizumab treatment was approved under the Initial treatment restriction, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be provided to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised tocilizumab treatment was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Patients are eligible to receive continuing tocilizumab treatment in courses of up to 24 weeks providing they continue to sustain the response.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for two infusions (one month supply). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 5 repeats will be authorised.

Where fewer than 5 repeats are requested at the time of initial application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

If a patient fails to respond to 2 courses of treatment they will not be eligible to receive further PBS-subsidised tocilizumab therapy in this treatment cycle. A patient may re-trial tocilizumab after a minimum of 12 months have elapsed between the date the last PBS-subsidised treatment was stopped and the date of the first application under a new treatment cycle

**Note**

Any queries concerning the arrangements to prescribe tocilizumab may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Further prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe tocilizumab should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

**Note**

TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying anti-rheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and
restrictions it refers to the tumour necrosis factor (TNF) α antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab) and the T-cell co-stimulation modulator (abatacept).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

PBS-subsidised abatacept, golimumab, infliximab and rituximab must be used in combination with methotrexate at a dose of at least 7.5 mg weekly. Where a patient cannot tolerate 7.5 mg of methotrexate weekly, they are eligible to receive PBS-subsidised adalimumab, certolizumab pegol, etanercept and tocilizumab.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-α antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:

(i) a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,

(ii) a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and

(iii) once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-α antagonists prior to 1 August 2010 please contact Medicare Australia on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD therapy is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or

(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or

(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or

(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab and tocilizumab. 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to Medicare Australia within 4 weeks.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:

Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient’s weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:

A further application may be submitted to Medicare Australia 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD...
supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialed.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept patients:

Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

Note

(3) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and Medicare Australia will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Note

TREATMENT OF PATIENTS WITH SEVERE ACTIVE SYSTEMIC JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of tocilizumab for a patient who has severe active systemic juvenile idiopathic arthritis (sJIA).

From 1 May 2012, a patient receiving PBS-subsidised tocilizumab therapy is considered to be in a treatment cycle. Under these arrangements, within a single treatment cycle, a patient may:

— continue to receive long-term treatment with PBS-subsidised tocilizumab while they continue to show a response to therapy, and
— fail to respond, or to sustain a response, to PBS-subsidised tocilizumab twice.

Once a patient has either failed or ceased to respond to 2 courses of treatment, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised tocilizumab therapy before they are eligible to receive further PBS-subsidised tocilizumab therapy. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised tocilizumab treatment was stopped to the date of the first application for initial treatment with tocilizumab under the new treatment cycle.

A patient who was receiving PBS-subsidised tocilizumab treatment immediately prior to 1 May 2012 is considered to be in their first cycle as of 1
A patient who has failed their first course of tocilizumab in a treatment cycle and who has a break in therapy of less than 12 months may commence a second course of treatment within the same treatment cycle.

A patient who has failed their first course of tocilizumab in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle.

(1) How to prescribe PBS-subsidised tocilizumab therapy after 1 May 2012.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised tocilizumab treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient wishes to re-commence treatment with tocilizumab following a break in PBS-subsidised therapy of more than 12 months (Initial 1); or

(iii) a patient has received the first course of PBS-subsidised (initial or continuing) tocilizumab therapy in a treatment cycle and is deemed to have failed to respond or sustain a response and the treating physician wishes to trial a second course (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab for that course.

For second and subsequent courses of PBS-subsidised tocilizumab, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with tocilizumab, a patient may qualify to receive up to 24 weeks of continuing treatment with tocilizumab providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing tocilizumab treatment in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted tocilizumab supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab.

(2) Treatment cycle.

Once initial treatment with PBS-subsidised tocilizumab is approved, a patient deemed to have failed to respond to the first course of treatment may have a second course without having to requalify with respect to the indices of disease severity (joint count, fever and/or CRP level and platelet count) or the prior therapy requirements, except if the patient has had a break in therapy of more than 12 months.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

(3) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the relevant baseline measurements of the joint count, fever and/or CRP level and platelet count submitted with the first authority application for tocilizumab.

Where a patient is deemed to have failed to respond or to sustain a response to the first course of therapy in a treatment cycle, prescribers may provide new baseline measurements for the second course of treatment within that cycle. Medicare Australia will assess response according to these revised baseline measurements. If new baseline measurements are not submitted with the initial application for the second course of treatment, then those submitted with the first course will be used by Medicare Australia to assess response to the second course.

(4) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised tocilizumab therapy of at least 12 months, must requalify for treatment under the Initial 1 treatment restriction.

(5) Patients ‘grandfathered’ onto PBS-subsidised treatment with tocilizumab.

A patient who commenced treatment with tocilizumab for severe active systemic juvenile idiopathic arthritis prior to 1 November 2011 and who continues to receive treatment at the time of application, may qualify for treatment under the initial ‘grandfather’ treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with tocilizumab will be authorised under this criterion.

Following completion of the initial PBS-subsidised course, further applications for treatment with tocilizumab will be assessed under the continuing treatment restriction.

‘Grandfather’ arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a ‘grandfather’ patient must qualify for initial treatment under the criteria that apply to a new patient. See ‘Re-commencement of treatment after a 12 month break in PBS-subsidised therapy’ above for further details.

(6) Withdrawal of treatment after sustained remission.
Withdrawal of treatment with tocilizumab should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to Medicare Australia at the time treatment is ceased.

**Note**
Special Pricing Arrangements apply.

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**TOCILIZUMAB**

**Authority required**
Initial 1 (new patient or patient re-commencing after a break of more than 24 months)

Initial PBS-subsidised treatment with tocilizumab, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults who:

(a) have severe active rheumatoid arthritis; and
(b) have received no PBS-subsidised treatment with a bDMARD for this condition in the previous 24 months; and
(c) have failed, in the 24 months immediately prior to the date of application, to achieve an adequate response to at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs), which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be:

— hydroxychloroquine at a dose of at least 200 mg daily; or
— leflunomide at a dose of at least 10 mg daily; or
— sulfasalazine at a dose of at least 2 g daily.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, then the 6 months of intensive DMARD treatment must include at least 3 months continuous treatment with each of at least 2 of the DMARDs:

— hydroxychloroquine at a dose of at least 200 mg daily; and/or
— leflunomide at a dose of at least 10 mg daily; and/or
— sulfasalazine at a dose of at least 2 g daily.

The application must include details of the contraindication or intolerance to methotrexate. Details of the toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose can be found on the Medicare Australia website [www.medicareaustralia.gov.au]. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

If 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved product information or cannot be tolerated at the doses specified above, then one or more of the following DMARDs may be used in place of these agents in order to satisfy the requirement for a trial of 6 months of intensive DMARD therapy with at least 2 DMARDs taken continuously for at least 3 months each:

— azathioprine at a dose of at least 1 mg/kg per day; and/or
— cyclosporin at a dose of at least 2 mg/kg/day; and/or
— sodium aurothiomalate at a dose of 50 mg weekly.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances. Details of the toxicities, including severity, which will be accepted as a reason for substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial can be found on the Medicare Australia website [www.medicareaustralia.gov.au].

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance and dose for each DMARD must be provided in the authority application. Details of the toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy can be found on the Medicare Australia website [www.medicareaustralia.gov.au].

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

(i) a total active joint count of at least 20 active (swollen and tender) joints; or
(ii) at least 4 active joints from the following list of major joints:

— elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
— shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are
due to active disease and not irreversible damage such as joint destruction or bony overgrowth). The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

1. a completed authority prescription form(s); and
2. a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and
3. a signed patient acknowledgement.

A maximum of 16 weeks of treatment will be authorised under this restriction.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials of appropriate strength, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 8 mg per kg. A separate authority prescription form must be completed for each strength requested.

Up to a maximum of 3 repeats of each strength may be authorised. Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Assessment of a patient’s response to an initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab.

Patients who fail to demonstrate a response to treatment with tocilizumab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition

**Authority required**

**Initial 2** (change or re-commencement after break of less than 24 months)

Initial course of PBS-subsidised treatment with tocilizumab, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults who:

(a) have a documented history of severe active rheumatoid arthritis; and

(b) have received prior PBS-subsidised bDMARD treatment for this condition and are eligible to receive further bDMARD therapy.

The authority application must be made in writing and must include:

1. a completed authority prescription form(s); and
2. a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

Applications for patients who have received PBS-subsidised treatment with tocilizumab and who wish to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient’s most recent course of PBS-subsidised tocilizumab treatment, within the timeframes specified below.

A maximum of 16 weeks of treatment will be authorised under this restriction.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials of appropriate strength, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 8 mg per kg. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats of each strength may be authorised.

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Where the most recent course of PBS-subsidised tocilizumab treatment was approved under either of the initial 1 or 2 treatment restrictions, patients must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be provided to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised tocilizumab treatment was approved under the continuing treatment criteria, patients must have been assessed for response, and the assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Patients who fail to demonstrate a response to treatment with tocilizumab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition

**Authority required**

**Continuing treatment**

Continuing PBS-subsidised treatment with tocilizumab, by a rheumatologist or clinical immunologist with expertise in the management of
TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying anti-rheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab) and the T-cell co-stimulation modulator (abatacept).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time. PBS-subsidised abatacept, golimumab, infliximab and rituximab must be used in combination with methotrexate at a dose of at least 7.5 mg weekly. Where a patient cannot tolerate 7.5 mg of methotrexate weekly, they are eligible to receive PBS-subsidised adalimumab, certolizumab pegol, etanercept and tocilizumab.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:
- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs
for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact Medicare Australia on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or

(ii) a patient wishes to re-commence treatment with a specific bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or

(iii) a patient has received prior PBS-subsidised bDMARD treatment and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or

(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab and tocilizumab. For certolizumab pegol (depending upon the dosing regimen), 6 to 20 weeks of therapy with certolizumab pegol, 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to Medicare Australia within 4 weeks.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:

Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient’s weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:

A further application may be submitted to Medicare Australia 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Rituximab patients:

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate [ESR], the C-reactive protein [CRP] levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the
requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled. Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept patients:

Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

**Note**

(3) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and Medicare Australia will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

**Note**

Special Pricing Arrangements apply.

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**Calcineurin inhibitors**

**CYCLOSPORIN**

**Authority required**

Management of rejection in patients following organ or tissue transplantation, under the supervision and direction of a transplant unit. Management includes initiation, stabilisation and review of therapy as required

**Authority required**

Management (which includes initiation, stabilisation and review of therapy) by dermatologists or clinical immunologists of patients with severe atopic dermatitis for whom other systemic therapies are ineffective or inappropriate

**Authority required**

Management (which includes initiation, stabilisation and review of therapy) by dermatologists of patients with severe psoriasis for whom other systemic therapies are ineffective or inappropriate and in whom the disease has caused significant interference with quality of life

**Authority required**

Management (which includes initiation, stabilisation and review of therapy) by nephrologists of patients with nephrotic syndrome in patients in whom steroids and cytostatic drugs have failed or are not tolerated or are considered inappropriate and in whom renal function is unimpaired

**Authority required**

Management (which includes initiation, stabilisation and review of therapy) by rheumatologists or clinical immunologists of patients with severe active rheumatoid arthritis for whom classical slow-acting anti-rheumatic agents (including methotrexate) are ineffective or inappropriate

**Caution**
### CYCLOSPORIN

**Authority required**
For use by organ or tissue transplant recipients

**Caution**
Careful monitoring of patients is mandatory.

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### TACROLIMUS

**Authority required**
Management of rejection in patients following organ or tissue transplantation, under the supervision and direction of a transplant unit. Management includes initiation, stabilisation and review of therapy as required

**Caution**
Careful monitoring of patients is mandatory.

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### Other immunosuppressants

**LENALIDOMIDE**

**Authority required**
Myelodysplastic syndrome

**Treatment Phase: Initial treatment**

**Clinical criteria:**
The treatment must be limited to a maximum duration of 16 weeks,

*AND*
Patient must be classified as Low risk or Intermediate-1 according to the International Prognostic Scoring System (IPSS),

*AND*
Patient must have a deletion 5q cytogenetic abnormality with or without additional cytogenetic abnormalities,
Patient must be red blood cell transfusion dependent.

Classification of a patient as Low risk requires a score of 0 on the IPSS, achieved with the following combination: less than 5% marrow blasts with good karyotypic status (normal, -Y alone, -5q alone, -20q alone), and 0/1 cytopenias.

Classification of a patient as Intermediate-1 requires a score of 0.5 to 1 on the IPSS, achieved with the following possible combinations:

1. 5%-10% marrow blasts with good karyotypic status (normal, -Y alone, -5q alone, -20q alone), and 0/1 cytopenias; OR
2. less than 5% marrow blasts with intermediate karyotypic status (other abnormalities), and 0/1 cytopenias; OR
3. less than 5% marrow blasts with good karyotypic status (normal, -Y alone, -5q alone, -20q alone), and 2/3 cytopenias; OR
4. less than 5% marrow blasts with intermediate karyotypic status (other abnormalities), and 2/3 cytopenias; OR
5. 5%-10% marrow blasts with intermediate karyotypic status (other abnormalities), and 0/1 cytopenias; OR
6. 5%-10% marrow blasts with good karyotypic status (normal, -Y alone, -5q alone, -20q alone), and 2/3 cytopenias; OR
7. less than 5% marrow blasts with poor karyotypic status (complex, greater than 3 abnormalities), and 0/1 cytopenias.

Classification of a patient as red blood cell transfusion dependent requires that:

(i) the patient has been transfused within the last 8 weeks; and
(ii) the patient has received at least 8 units of red blood cell in the last 6 months prior to commencing PBS-subsidised therapy with lenalidomide; and would be expected to continue this requirement without lenalidomide treatment.

Patients receiving lenalidomide under the PBS listing must be registered in the i-access risk management program.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and
(b) a completed Myelodysplastic Syndrome Lenalidomide Authority Application - Supporting Information Form; and
(c) a copy of the bone marrow biopsy report demonstrating that the patient has myelodysplastic syndrome; and
(d) a copy of the full blood examination report; and
(e) a copy of the pathology report detailing the cytogenetics demonstrating Low risk or Intermediate-1 disease according to the IPSS (note: using Fluorescence in Situ Hybridization (FISH) to demonstrate MDS -5q is acceptable); and
(f) details of transfusion requirements including: (i) the date of most recent transfusion and the number of red blood cell units transfused; and (ii) the total number of red cell units transfused in the 4 and 6 months preceding the date of this application; and
(g) a signed patient acknowledgement form.

Note
Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Note
Special Pricing Arrangements apply.

Authority required
Myelodysplastic syndrome
Treatment Phase: Continuing treatment

Clinical criteria:

Patient must be classified as Low risk or Intermediate-1 according to the International Prognostic Scoring System (IPSS),

AND

Patient must have a deletion 5q cytogenetic abnormality with or without additional cytogenetic abnormalities,

AND

Patient must have received PBS-subsidised initial therapy with lenalidomide for myelodysplastic syndrome,

AND

Patient must have achieved and maintained transfusion independence; or least a 50% reduction in red blood cell unit transfusion requirements compared with the four month period prior to commencing initial PBS-subsidised therapy with lenalidomide,

AND

Patient must not have progressive disease.
Patients receiving lenalidomide under the PBS listing must be registered in the i-access risk management program.

The first authority application for continuing supply must be made in writing. Subsequent authority applications for continuing supply may be made by telephone.

The following evidence of response must be provided at each application:
(i) a haemoglobin level taken within the last 4 weeks; and
(ii) the date of the last transfusion; and
(iii) a statement of the number of units of red cells transfused in the 4 months immediately preceding this application; and
(iv) a statement confirming that the patient has not progressed to acute myeloid leukaemia.

Note
Written applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Note
Subsequent authority applications for continuing treatment may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Note
Special Pricing Arrangements apply.

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LENALIDOMIDE
Authority required
Multiple myeloma
Treatment Phase: Initial PBS-subsidised treatment

Clinical criteria:
The condition must be confirmed by a histological diagnosis,

AND
The treatment must be as monotherapy; OR
The treatment must be in combination with dexamethasone,

AND
Patient must have progressive disease after at least one prior therapy,

AND
Patient must have undergone or be ineligible for a primary stem cell transplant,

AND
Patient must have experienced treatment failure after a trial of at least four (4) weeks of thalidomide at a dose of at least 100 mg daily or have failed to achieve at least a minimal response after eight (8) or more weeks of thalidomide-based therapy for progressive disease,

AND
Patient must not be receiving concomitant PBS-subsidised bortezomib.

Progressive disease is defined as at least 1 of the following:
(a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or
(b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or
(c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase of the difference between involved free light chain and uninvolved free light chain; or
(d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or
(e) an increase in the size or number of lytic bone lesions (not including compression fractures); or
(f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or
(g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.
**Thalidomide treatment failure is defined as:**

1. confirmed disease progression during thalidomide treatment or within 6 months of discontinuing thalidomide treatment; or
2. severe intolerance or toxicity unresponsive to clinically appropriate dose adjustment.

Severe intolerance due to thalidomide is defined as unacceptable somnolence or sedation interfering with activities of daily living.

Toxicity from thalidomide is defined as peripheral neuropathy (Grade 2 or greater, interfering with function), drug-related seizures, serious Grade 3 or 4 drug-related dermatological reactions, such as Stevens-Johnson Syndrome, or other Grade 3 or 4 toxicity.

Failure to achieve at least a minimal response after 8 or more weeks of thalidomide-based therapy for progressive disease is defined as:

1. less than a 25% reduction in serum or urine M protein; or
2. in oligo-secretory and non-secretory myeloma patients only, less than a 25% reduction in the difference between involved and uninvolved serum free light chain levels.

If the dosing requirement for thalidomide cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:

1. a completed authority prescription form; and
2. a completed Multiple Myeloma lenalidomide Authority Application - Supporting Information Form, which includes details of the histological diagnosis of multiple myeloma, prior treatments including name(s) of drug(s) and date of most recent treatment cycle and record of prior stem cell transplant or ineligibility for prior stem cell transplant; details of thalidomide treatment failure; details of the basis of the diagnosis of progressive disease or failure to respond; and nomination of which disease activity parameters will be used to assess response; and
3. duration of thalidomide and daily dose prescribed; and
4. a signed patient acknowledgment.

To enable confirmation of eligibility for treatment, current diagnostic reports of at least one of the following must be provided:

(a) the level of serum monoclonal protein; or
(b) Bence-Jones proteinuria - the results of 24-hour urinary light chain M protein excretion; or
(c) the serum level of free kappa and lambda light chains; or
(d) bone marrow aspirate or trephine; or
(e) if present, the size and location of lytic bone lesions (not including compression fractures); or
(f) if present, the size and location of all soft tissue plasmacytomas by clinical or radiographic examination i.e. MRI or CT-scan; or
(g) if present, the level of hypercalcaemia, corrected for albumin concentration.

As these parameters will be used to determine response, results for either (a) or (b) or (c) should be provided for all patients. Where the patient has oligo-secretory or non-secretory multiple myeloma, either (c) or (d) or if relevant (e), (f) or (g) should be provided. Where the prescriber plans to assess response in patients with oligo-secretory or non-secretory multiple myeloma with free light chain assays, evidence of the oligo-secretory or non-secretory nature of the multiple myeloma (current serum M protein less than 10 g per L) must be provided.

Patients receiving lenalidomide under the PBS listing must be registered in the i-access risk management program.

**Note**

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

**Note**

Special Pricing Arrangements apply.

**Authority required**

Multiple myeloma

Treatment Phase: Continuing PBS-subsidised treatment

**Clinical criteria:**

Patient must have previously received an authority prescription for lenalidomide,

AND

Patient must not have progressive disease,

AND

The treatment must be as monotherapy; OR
The treatment must be in combination with dexamethasone.

Progressive disease is defined as at least 1 of the following:

(a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or
(b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or
(c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase of the difference between involved free light chain and uninvolved free light chain; or
(d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or
(e) an increase in the size or number of lytic bone lesions (not including compression fractures); or
(f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or
(g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Patients receiving lenalidomide under the PBS listing must be registered in the i-access risk management program.

Note

Authority applications for continuing treatment may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Note

Written applications for authority to prescribe should be forwarded to:

Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Note

Special Pricing Arrangements apply.

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RITUXIMAB

Authority required

Initial 1 (patient re-commencing after a break of more than 24 months)

Initial PBS-subsidised treatment with rituximab, in combination with methotrexate at a dose of at least 7.5 mg weekly, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults who:

(a) have severe active rheumatoid arthritis; and
(b) have failed to respond to at least 1 PBS-subsidised TNF-alfa antagonist; and
(c) have received no PBS-subsidised treatment with a bDMARD for this condition in the previous 24 months; and
(d) have failed, in the 24 months immediately prior to the date of application, to achieve an adequate response to at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs), which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be:

— hydroxychloroquine at a dose of at least 200 mg daily; or
— leflunomide at a dose of at least 10 mg daily; or
— sulfasalazine at a dose of at least 2 g daily.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, then the 6 months of intensive DMARD treatment must include at least 3 months continuous treatment with each of at least 2 of the DMARDs:

— hydroxychloroquine at a dose of at least 200 mg daily; and/or
— leflunomide at a dose of at least 10 mg daily; and/or
— sulfasalazine at a dose of at least 2 g daily.

The application must include details of the contraindication or intolerance to methotrexate. Details of the toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose can be found on the Medicare Australia website [www.medicareaustralia.gov.au]. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

If 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved
Patients who fail to demonstrate a response to rituximab treatment and who qualify to trial an alternate bDMARD according to the

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**Highly Specialised Drugs Program (Private Hospital)**

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**Authority required**

Initial 2 (change or re-commencement after break of less than 24 months)

Initial course of PBS-subsidised treatment with rituximab, in combination with methotrexate at a dose of at least 7.5 mg weekly, by a

---

**Rheumatoid Arthritis PBS Authority Application - Supporting Information Form**

(1) a completed authority prescription form; and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website [www.medicareaustralia.gov.au]]; and

(3) a signed patient acknowledgement.

A maximum of two infusions will be authorised under this restriction.

Assessment of a patient’s response to an initial course of treatment must be made at least 12 weeks after the first infusion so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia within 4 weeks of the date it was conducted. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with rituximab.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction.

Patients who fail to demonstrate a response to treatment with rituximab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Patients who fail to demonstrate a response to rituximab treatment and who qualify to trial an alternate bDMARD according to the interchangeability arrangements for bDMARDs for the treatment of severe rheumatoid arthritis, may do so without having to have a 22 week treatment-free period

---

**Authority required**

Initial 2 (change or re-commencement after break of less than 24 months)

Initial course of PBS-subsidised treatment with rituximab, in combination with methotrexate at a dose of at least 7.5 mg weekly, by a

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**Rheumatoid Arthritis PBS Authority Application - Supporting Information Form**

(1) a completed authority prescription form; and

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(3) a signed patient acknowledgement.

A maximum of two infusions will be authorised under this restriction.

Assessment of a patient’s response to an initial course of treatment must be made at least 12 weeks after the first infusion so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia within 4 weeks of the date it was conducted. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with rituximab.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction.

Patients who fail to demonstrate a response to treatment with rituximab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Patients who fail to demonstrate a response to rituximab treatment and who qualify to trial an alternate bDMARD according to the interchangeability arrangements for bDMARDs for the treatment of severe rheumatoid arthritis, may do so without having to have a 22 week treatment-free period
The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

Applications for patients who have received PBS-subsidised treatment with rituximab and who wish to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient’s most recent course of PBS-subsidised rituximab treatment, within the timeframes specified below.

A maximum of two infusions will be authorised under this restriction.

Where the most recent course of PBS-subsidised rituximab treatment was approved under either of the initial 1 or 2 treatment restrictions patients must be assessed for response at least 12 weeks after the first infusion. This assessment must be provided to Medicare Australia no later than 4 weeks from the date of assessment.

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent provided they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The demonstration of response must be submitted to Medicare Australia within 4 weeks of assessment.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. Patients who fail to demonstrate a response to treatment with rituximab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Patients who fail to demonstrate a response to rituximab treatment and who qualify to trial an alternate bDMARD according to the interchangeability arrangements for bDMARDs for the treatment of severe rheumatoid arthritis, may do so without having to have a 22 week treatment-free period

**Authority required**

Continuing treatment

Continuing PBS-subsidised treatment with rituximab, in combination with methotrexate at a dose of at least 7.5 mg weekly, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults:

(a) who have a documented history of severe active rheumatoid arthritis; and

(b) who have demonstrated an adequate response to treatment with rituximab; and

(c) whose most recent course of PBS-subsidised bDMARD treatment was with rituximab.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(i) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(ii) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

— elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

— shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

A maximum of two infusions will be authorised under this restriction.

Patients may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The demonstration of response must be submitted to Medicare Australia within 4 weeks of assessment.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction.

Patients who fail to demonstrate a response to treatment with rituximab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition

**Note**

Any queries concerning the arrangements to prescribe rituximab may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Further prescribing information (including Authority Application Forms) is on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe rituximab should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826
TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

Note

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying anti-rheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) α antagonist (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab) and the T-cell co-stimulation modulator (abatacept).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

PBS-subsidised abatacept, golimumab, infliximab and rituximab must be used in combination with methotrexate at a dose of at least 7.5 mg weekly. Where a patient cannot tolerate 7.5 mg of methotrexate weekly, they are eligible to receive PBS-subsidised adalimumab, certolizumab pegol, etanercept and tocilizumab.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-α antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:

- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-α antagonists prior to 1 August 2010 please contact Medicare Australia on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab and tocilizumab, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to Medicare Australia within 4 weeks.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:

Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient’s weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:

A further application may be submitted to Medicare Australia 24 weeks after the first infusion. New baselines may be submitted with this
application if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept patients:

Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

Note

(3) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and Medicare Australia will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Note

Special Pricing Arrangements apply.

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Multiple myeloma

**Caution**
Thalidomide is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and for 1 month after cessation of treatment.

**Note**
Patients receiving thalidomide under the PBS listing must be registered in the i-access risk management program.

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## MUSCULO-SKELETAL SYSTEM

### MUSCLE RELAXANTS

**MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS**

*Other centrally acting agents*

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### DRUGS FOR TREATMENT OF BONE DISEASES

**DRUGS AFFECTING BONE STRUCTURE AND MINERALIZATION**

*Bisphosphonates*

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**PAMIDRONATE DISODIUM**

*Authority required*

Hypercalcaemia of malignancy

Clinical criteria:

Patient must have a malignancy refractory to anti-neoplastic therapy.

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**PAMIDRONATE DISODIUM**

*Authority required*

Hypercalcaemia of malignancy

Clinical criteria:

Patient must have a malignancy refractory to anti-neoplastic therapy.

**Note**

Pharmaceutical benefits that have the form disodium pamidronate powder for I.V. infusion 30 mg (after reconstitution) and pharmaceutical benefits that have the form disodium pamidronate concentrated injection 30 mg are equivalent for the purposes of substitution.

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**Hypercalcaemia of malignancy**

Clinical criteria:
Patient must have a malignancy refractory to anti-neoplastic therapy.

Authority required
Multiple myeloma

Authority required
Bone metastases

Clinical criteria:
The condition must be due to breast cancer.

Note
Pharmaceutical benefits that have the form disodium pamidronate powder for i.v. infusion 90 mg (after reconstitution) and pharmaceutical benefits that have the form disodium pamidronate concentrated injection 90 mg are equivalent for the purposes of substitution.
## NERVOUS SYSTEM

### ANTI-PARKINSON DRUGS

#### DOPAMINERGIC AGENTS

**Dopa and dopa derivatives**

**Levodopa + Carbidopa Anhydrous**

*Authority required*

Management of advanced Parkinson disease in a patient with severe disabling motor fluctuations not adequately controlled by oral therapy.

Treatment must be commenced in a hospital-based movement disorder clinic

*Note*

Patients should have adequate cognitive function to manage administration with a portable continuous infusion pump.

A positive clinical response to Duodopa administered via a temporary nasoduodenal tube should be confirmed before a permanent percutaneous endoscopic gastrostomy (PEG) tube is inserted.

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**Dopamine agonists**

**Apomorphine**

*Authority required*

Parkinson’s disease in patients severely disabled by motor fluctuations which do not respond to other therapy

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### PSYCHOLEPTICS

#### Antipsychotics

**Diazepines, oxazepines, thiazepines and oxepines**

**Clozapine**

*Authority required*

Schizophrenia

Clinical criteria:

Patient must be non-responsive to other neuroleptic agents; OR

Patient must be intolerant of other neuroleptic agents.

A medical practitioner should request a quantity sufficient for up to one month’s supply. Up to 5 repeats will be authorised.

*Note*

Patients receiving clozapine under the PBS listing must be registered in a clozapine patient monitoring program; Novartis Clozaril Patient Monitoring System (CPMSplus) or Clopineconnect.

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RESPIRATORY SYSTEM

DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES

OTHER SYSTEMIC DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES

OMALIZUMAB

Authority required

Initial treatment of uncontrolled severe allergic asthma

Initial PBS-subsidised treatment with omalizumab by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma, of a patient aged 12 years or older with uncontrolled severe allergic asthma who has been under the care of this physician for at least 12 months, and satisfies the following criteria:

(a) has a diagnosis of asthma confirmed and documented by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma, defined by standard clinical features, including:

(i) forced expiratory volume (FEV1) reversibility greater than or equal to 12% and greater than or equal to 200 mL at baseline within 30 minutes after administration of salbutamol (200 to 400 micrograms), or

(ii) airway hyperresponsiveness defined as a greater than 20% decline in FEV1 during a direct bronchial provocation test or greater than 15% decline during an indirect bronchial provocation test, or

(iii) peak expiratory flow (PEF) variability of greater than 15% between the two highest and two lowest peak expiratory flow rates during 14 days; and

(b) duration of asthma of at least 1 year; and

(c) FEV1 less than or equal to 80% predicted, documented on 3 or more occasions in the previous 12 months; and

(d) past or current evidence of atopy, documented by skin prick testing or RAST; and

(e) total serum human immunoglobulin E (IgE) greater than or equal to 76 IU/mL; and

(f) has signed a patient acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criteria for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and

(g) has failed to achieve adequate control with optimised asthma therapy, despite formal assessment of and adherence to correct inhaler technique, which has been documented (see NOTE). Optimised asthma therapy includes:

(i) adherence to maximal inhaled therapy, including high dose inhaled corticosteroid (budesonide 1600 micrograms per day or fluticasone propionate 1000 micrograms per day or equivalent), plus long-acting beta-2 agonist therapy (at least salmeterol 50 micrograms bd or eformoterol 12 micrograms bd) for at least 12 months, unless contraindicated or not tolerated, AND

(ii) oral corticosteroids (at least 10 mg per day prednisolone (or equivalent)) for at least 6 weeks, unless contraindicated or not tolerated.

If the requirement for treatment with optimised asthma therapy cannot be met because of contraindications according to the relevant TGA-approved Product Information and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the authority application. Details of the accepted toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement of treatment with optimised asthma therapy can be found on the Medicare Australia website [www.medicareaustralia.gov.au].

The initial IgE assessment must be no more than 12 months old at the time of application. A re-assessment of free IgE can only be made at least 12 months after the last dose of omalizumab. For patients re-commencing omalizumab within 12 months of the last dose the previous pre-omalizumab IgE level should be used.

The IgE pathology report must be provided with the authority application.

The following initiation criteria indicate failure to achieve adequate control and must be demonstrated in all patients at the time of the application:

(a) an Asthma Control Questionnaire (ACQ-5) score of at least 2.0, as assessed in the previous month, AND

(b) while on oral corticosteroids and in the past 12 months, experienced at least 1 admission to hospital for a severe asthma exacerbation, OR 1 severe asthma exacerbation, requiring documented use of systemic corticosteroids (oral corticosteroids initiated or increased for at least 3 days, or parenteral corticosteroids) prescribed/supervised by a physician.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Allergic Asthma PBS Authority Application - Supporting Information Form (may be downloaded from the Medicare Australia website [www.medicareaustralia.gov.au]) which includes the following:

(i) details of prior optimised asthma drug therapy (dosage, date of commencement and duration of therapy); and

(ii) details of severe exacerbation/s experienced while on oral corticosteroids (date and treatment); and

(iii) the signed patient acknowledgement; and

(c) a completed Asthma Control Questionnaire (ACQ-5) calculation sheet including the date of assessment of the patient’s symptoms. (For copies of the ACQ please contact Novartis Medical Information on 1800 671 203 or medinfo.phauno@novartis.com)

At the time of the authority application, medical practitioners should request the appropriate maximum quantity and number of repeats to provide for an initial course of omalizumab consisting of the recommended number of doses for the baseline IgE level and body weight of the patient (refer
eligible to receive further PBS-subsidised treatment with omalizumab for this condition within 6 months of the date on which treatment was ceased (refer to the TGA-approved Product Information).

Where fewer than the required number of repeats to complete 28 weeks of treatment are requested at the time of the application, authority approvals for sufficient repeats to complete 28 weeks of omalizumab therapy may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period beyond 28 weeks.

The Asthma Control Questionnaire (5 item version) assessment of the patient’s response to this initial course of treatment, and the assessment of oral corticosteroid dose, must be made at around 24 to 26 weeks after the first dose so that there is adequate time for a response to be demonstrated and for the application for continuing therapy to be processed.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia within 4 weeks of the date of assessment, and no later than 2 weeks prior to the patient completing their current treatment course, to avoid an interruption to supply. Where a response assessment is not undertaken and submitted to Medicare Australia within this timeframe, the patient will be deemed to have failed to respond to treatment with omalizumab. It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 24 to 26 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised omalizumab treatment.

A patient who fails to respond to a course of PBS-subsidised omalizumab for the treatment of uncontrolled severe allergic asthma will not be eligible to receive further PBS-subsidised treatment with omalizumab for this condition within 6 months of the date on which treatment was ceased.

**Authority required**

Continuing treatment

Continuing PBS-subsidised treatment with omalizumab, by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma, of a patient who:

(a) has a diagnosis of asthma confirmed and documented by a respiratory physician, clinical immunologist, allergist or general physician who:

(b) has demonstrated or sustained an adequate response to treatment with omalizumab.

An adequate response to omalizumab treatment is defined as:

(a) a reduction in the Asthma Control Questionnaire (ACQ-5) score of at least 0.5 from baseline, OR

(b) maintenance oral corticosteroid dose reduced by at least 25% from baseline, and no deterioration in ACQ-5 score from baseline.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Allergic Asthma PBS Authority Application - Supporting Information Form (may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)) which includes details of maintenance oral corticosteroid dose; and

(c) a completed Asthma Control Questionnaire (ACQ-5) calculation sheet including the date of assessment of the patient’s symptoms. (For copies of the ACQ please contact Novartis Medical Information on 1800 671 203 or medinfo.phauno@novartis.com)

All applications for continuing treatment with omalizumab must include a measurement of response to the prior course of therapy. The Asthma Control Questionnaire (5 item version) assessment of the patient’s response to the prior course of treatment, and the assessment of oral corticosteroid dose, must be made at around 20 to 22 weeks after the first dose so that there is adequate time for a response to be demonstrated and for the application for continuing therapy to be processed.

The first assessment should, where possible, be completed by the same physician who initiated treatment with omalizumab. If the same physician cannot assess the patient please call Medicare Australia on 1800 700 270.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia within 4 weeks of the date of assessment, and no later than 2 weeks prior to the patient completing their current treatment course, to avoid an interruption to supply. Where a response assessment is not undertaken and submitted to Medicare Australia within this timeframe, the patient will be deemed to have failed to respond to treatment with omalizumab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 20 to 22 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised omalizumab treatment.

Patients are eligible to receive continuing courses of omalizumab treatment of up to 24 weeks providing they continue to demonstrate an adequate response to treatment.

At the time of the authority application, medical practitioners should request the appropriate maximum quantity and number of repeats to provide for a continuing course of omalizumab consisting of the recommended number of doses for the baseline IgE level and body weight of the patient (refer to the TGA-approved Product Information), sufficient for 24 weeks of therapy.

Where fewer than the required number of repeats to complete 24 weeks of treatment are requested at the time of the application, authority approvals for sufficient repeats to complete 24 weeks of omalizumab therapy may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

A patient who fails to respond to a course of PBS-subsidised omalizumab for the treatment of uncontrolled severe allergic asthma will not be eligible to receive further PBS-subsidised treatment with omalizumab for this condition within 6 months of the date on which treatment was ceased.

**Authority required**

Initial PBS-subsidised treatment of severe allergic asthma in a patient who has previously received non-PBS-subsidised therapy with omalizumab (grandfather patients)

Initial PBS-subsidised supply for continuing treatment with omalizumab by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma, of a patient aged 12 years or older with severe allergic asthma who satisfies the following criteria:

(a) has a diagnosis of asthma confirmed and documented by a respiratory physician, clinical immunologist, allergist or general physician...
The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Allergic Asthma PBS Authority Application - PBS-subsidised therapy with omalizumab should be used for the assessment.

(i) adherence to maximal inhaled therapy, including high dose inhaled corticosteroid (budesonide 1600 micrograms per day or fluticasone propionate 1000 micrograms per day or equivalent), plus long-acting beta-2 agonist therapy (at least salmeterol 50 micrograms bd or eformoterol 12 micrograms bd) for at least 12 months, and

(ii) may have included maintenance dose oral corticosteroids; and

(f) has demonstrated an adequate response to treatment with omalizumab. A review of the patient’s records should be conducted to extract pre- and post-omalizumab data on symptoms, quality of life, medication doses, exacerbations and hospitalisations. Examples of parameters to establish response include:

(i) a reduction in Asthma Control Questionnaire (ACQ-5) score of at least 0.5;

(ii) an improvement of at least 0.5 in the Asthma Quality of Life Questionnaire (AQLQ or mini-AQLQ);

(iii) maintenance oral corticosteroid dose reduced by at least 25% from baseline; and/or

(iv) a reduction in the number of hospitalisations or severe exacerbations requiring use of systemic corticosteroids, compared to the 12 months prior to commencement of omalizumab.

Where baseline assessments are not available, please call Medicare Australia on 1800 700 270 to discuss.

If the requirement for treatment with optimised asthma therapy cannot be met because of contraindications according to the relevant TGA-approved Product Information and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the authority application. Details of the accepted contraindications and toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement of treatment with optimised asthma therapy can be found on the Medicare Australia website [www.medicareaustralia.gov.au].

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Allergic Asthma PBS Authority Application - Supporting Information Form (may be downloaded from the Medicare Australia website www.medicareaustralia.gov.au) which includes the following:

(i) details of prior optimised asthma drug therapy (dosage, date of commencement and duration of therapy); and

(ii) details of pre- and post-omalizumab data on symptoms, quality of life, medication doses, exacerbations and hospitalisations; and

(iii) the signed patient acknowledgement.

At the time of the authority application, medical practitioners should request the appropriate maximum quantity and number of repeats to provide for an initial course of omalizumab consisting of the recommended number of doses for the baseline IgE level and body weight of the patient (refer to the TGA-approved Product Information) and ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised omalizumab treatment. It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 20 to 22 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised omalizumab treatment.

Patients are eligible to receive continuing courses of omalizumab treatment of up to 24 weeks providing they continue to demonstrate an adequate response to treatment.

Patients may qualify for PBS-subsidised treatment under this restriction once only. A patient who fails to respond to a course of PBS-subsidised omalizumab for the treatment of uncontrolled severe allergic asthma will not be eligible to receive further PBS-subsidised treatment with omalizumab for this condition within 6 months of the date on which treatment was ceased.
### TREATMENT OF ADULT AND ADOLESCENT PATIENTS WITH UNCONTROLLED SEVERE ALLERGIC ASTHMA

Patients are eligible to commence an 'omalizumab treatment cycle' (initial treatment course with or without continuing treatment course/s) if they satisfy the eligibility criteria as detailed under the initial treatment restriction.

Once a patient has either failed to achieve or maintain a response to omalizumab, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 6 month break in PBS-subsidised omalizumab therapy before they are eligible to commence the next cycle. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised omalizumab treatment is stopped to the date of the first application for initial treatment with omalizumab under the new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised omalizumab therapy.

(a) Initial treatment.

Applications for initial treatment should be made where a patient has received no prior PBS-subsidised omalizumab treatment in this treatment cycle and wishes to commence such therapy.

Initial treatment authorisations will be limited to provide for a maximum of 28 weeks of therapy with omalizumab.

A patient must be assessed for response to a course of Initial PBS-subsidised treatment following a minimum of 24 weeks of therapy with omalizumab, and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date of assessment.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with omalizumab.

For second and subsequent courses of PBS-subsidised omalizumab treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of the initial treatment course with omalizumab, a patient may qualify to receive up to a further 24 weeks of continuing treatment with omalizumab providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing omalizumab treatment in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted omalizumab supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia within 4 weeks of the date of assessment, and no later than 2 weeks prior to the patient completing their current treatment course, to avoid an interruption to supply.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with omalizumab.

(2) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the Asthma Control Questionnaire (ACQ-5 item version) and oral corticosteroid dose, submitted with the initial authority application for omalizumab. However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and Medicare Australia will assess response according to these revised baseline measurements.

(3) Re-commencement of treatment after a 6 month break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised omalizumab therapy of at least 6 months, must re-qualify for initial treatment with respect to the indices of disease severity (oral corticosteroid dose, Asthma Control Questionnaire (ACQ-5) score, and relevant exacerbation history). Patients must have received optimised standard therapy, at adequate doses and for the minimum period specified, immediately prior to the time the new baseline assessments are performed.

(4) Patients ‘grandfathered’ onto PBS-subsidised treatment with omalizumab.

A patient who commenced treatment with omalizumab for uncontrolled severe allergic asthma prior to 1 November 2010 and who continues to receive treatment at the time of application, may qualify for treatment under the Initial ‘grandfather’ treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with omalizumab will be authorised under this criterion.

Following completion of the Initial PBS-subsidised course, further applications for treatment with omalizumab will be assessed under the continuing treatment restriction.
'Grandfather' arrangements will only apply for the first treatment cycle (initial treatment course with or without continuing treatment course/s). For the second and subsequent cycles, a 'Grandfathered' patient must re-qualify for initial treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 6 month break in PBS-subsidised therapy' above for further details.

(5) Monitoring of patients.

Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medications for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

Note

Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at www.medicareaustralia.gov.au or www.nationalasthma.org.au); the assessment and adherence to correct technique should be documented in the patient’s medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).

Note

Special Pricing Arrangements apply.

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>Qty</th>
<th>Brand Name and Manufacturer</th>
</tr>
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<td>9746Y</td>
<td>omalizumab 150 mg injection [1 x 150 mg vial] (&amp;) inert substance diluent [1 x 1.2 mL ampoule], 1 pack</td>
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<td>Xolair NV</td>
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<td>10122R</td>
<td>omalizumab 150 mg/mL injection, 1 x 1 mL syringe</td>
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<td>378.04</td>
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<td>10110D</td>
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<td>Xolair NV</td>
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</tbody>
</table>

COUGH AND COLD PREPARATIONS

EXpectorants, EXCL. COMBINATIONS WITH COUGH SUPPRESSANTS

Mucolytics

DORNASE ALFA

Authority required

Cystic fibrosis

Clinical criteria:

Patient must have a forced vital capacity (FVC) greater than 40% predicted for age, gender and weight, AND

Patient must have evidence of chronic suppurative lung disease (cough and sputum most days of the week, or greater than 3 respiratory tract infections of more than 2 weeks’ duration in any 12 months, or objective evidence of obstructive airways disease).

Population criteria:

Patient must be 5 years of age or older.

Patient must be assessed at a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis. The prescribing of dornase alfa therapy under the HSD program is limited to such physicians. If attendance at such a unit is not possible because of geographical isolation, management (including prescribing) may be by a specialist physician or paediatrician in consultation with such a unit.

The measurement of lung function is to be conducted by independent (other than the treating doctor) experienced personnel at an established lung function testing laboratory, unless this is not possible because of geographical isolation.

Prior to dornase alfa therapy, a baseline measurement of forced expiratory volume in 1 second (FEV1) must be undertaken during a stable period of the disease.

Initial therapy is limited to 3 months treatment with dornase alfa at a dose of 2.5 mg daily.

FEV1 measurement (single test under conditions as above) and a global assessment of the patient involving the patient, the patient’s family (in the case of paediatric patients), the treating physician(s) and an additional independent member of the cystic fibrosis treatment team must be undertaken and documented following 3 months of initial therapy.

To be eligible for continued PBS-subsidised treatment with dornase alfa following 3 months of initial treatment:

(1) the patient must demonstrate no deterioration in FEV1 compared to baseline; AND

(2) the patient or the patient’s family (in the case of paediatric patients) must report improvement in the patient’s airway clearance; AND

(3) the treating physician(s) must report a benefit in the clinical status of the patient.

Further reassessments involving the patient, the patient’s family (in the case of paediatric patients), the treating physician(s) and an additional independent member of the cystic fibrosis treatment team must be undertaken and documented at six-monthly intervals to establish that all agree that dornase alfa treatment is continuing to produce worthwhile benefits. Dornase alfa therapy should cease if there is not general agreement of benefit as there is always the possibility of harm from unnecessary use.

Other aspects of treatment, such as physiotherapy, must be continued.

Where there is documented evidence that a patient already receiving dornase alfa therapy would have met the criteria for subsidy, then the patient is eligible to continue treatment under the HSD program. Where such evidence is not available, patients will need to satisfy the initiation and
Continuation criteria as for new patients. (Four weeks is considered a suitable wash-out period.)

**Authority required**

**Cystic fibrosis**

**Clinical criteria:**

- Patient must have a severe clinical course with frequent respiratory exacerbations or chronic respiratory symptoms (including chronic or recurrent cough, wheeze or tachypnoea) requiring hospital admissions more frequently than 3 times per year; OR
- Patient must have significant bronchiectasis on chest high resolution computed tomography scan; OR
- Patient must have severe cystic fibrosis bronchiolitis with persistent wheeze non-responsive to conventional medicines; OR
- Patient must have severe physiological deficit measure by forced oscillation technique or multiple breath nitrogen washout and failure to respond to conventional therapy.

**Population criteria:**

- Patient must be less than 5 years of age.
- Patient must be assessed at a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis. The prescribing of dornase alfa therapy under the HSD program is limited to such physicians. If attendance at such a unit is not possible because of geographical isolation, management (including prescribing) may be by a specialist physician or paediatrician in consultation with such a unit.
- Following an initial 6 months therapy, a comprehensive assessment must be undertaken and documented involving the patient, the patient’s family, the treating physician and an additional independent member of the cystic fibrosis treatment team to establish agreement that dornase alfa treatment is continuing to produce worthwhile benefit. Treatment with dornase alfa should cease if there is not agreement of benefit, as there is always the possibility of harm from unnecessary use. Further reassessments must be undertaken and documented at six-monthly intervals.

**Authority required**

**Cystic fibrosis**

**Treatment Phase: Continuing treatment**

**Clinical criteria:**

- Patient must have initiated treatment with dornase alfa at an age of less than 5 years, AND
- Patient must have undergone a comprehensive assessment, involving the patient’s family, the treating physician and an additional independent member of the cystic fibrosis treatment team which documents agreement that dornase alfa treatment is continuing to produce worthwhile benefit.

**Population criteria:**

- Patient must be 5 years of age or older.
- Further reassessments must be undertaken and documented at six-monthly intervals. Treatment with dornase alfa should cease if there is not agreement of benefit as there is always the possibility of harm from unnecessary use.

**Authority required**

**Cystic fibrosis**

**Clinical criteria:**

- Patient must have initiated treatment with dornase alfa prior to 1 November 2009, AND
- Patient must have undergone a comprehensive assessment, involving the patient’s family, the treating physician and an additional independent member of the cystic fibrosis treatment team which documents agreement that dornase alfa treatment is continuing to produce worthwhile benefit.

**Population criteria:**

- Patient must be less than 5 years of age.
- Further reassessments must be undertaken and documented at six-monthly intervals. Treatment with dornase alfa should cease if there is not agreement of benefit as there is always the possibility of harm from unnecessary use.

**Note**

Dornase alfa is not PBS-subsidised for use in combination with PBS-subsidised mannitol.

**Note**

It is highly desirable that all patients be included in the national cystic fibrosis patient database.

**Code:** 6120D

**Brand Name and Manufacturer:** Pulmozyme

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty</th>
<th>No. of Rpts</th>
<th>Premium $</th>
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<td>6120D</td>
<td>dornase alfa 2.5 mg/2.5 mL inhalation: solution, 30 x 2.5 mL ampoules</td>
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</table>

**MANNITOL**

**Authority required**

**Cystic fibrosis**

**Clinical criteria:**

- Patient must have been assessed for bronchial hyperresponsiveness as per the TGA approved Product Information mannitol initiation dose.
assessment, prior to mannitol therapy. If the patient has a negative hyperresponsiveness test they may be eligible for PBS subsidised treatment with mannitol.

AND

Patient must have a forced expiratory volume in 1 second (FEV1) greater than 30% predicted for age, gender and height,

AND

Patient must be intolerant or inadequately responsive to dornase alfa,

AND

Patient must have evidence of chronic suppurative lung disease (cough and sputum most days of the week, or greater than 3 respiratory tract infections of more than 2 weeks' duration in any 12 months, or objective evidence of obstructive airways disease).

Population criteria:

Patient must be 6 years of age or older.

Patient must be assessed at a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis. The prescribing of mannitol therapy under the HSD program is limited to such physicians. If attendance at such a unit is not possible because of geographical isolation, management (including prescribing) may be by a specialist physician or paediatrician in consultation with such a unit.

The measurement of lung function is to be conducted by independent (other than the treating doctor) experienced personnel at an established lung function testing laboratory, unless this is not possible because of geographical isolation.

Prior to mannitol therapy, a baseline measurement of FEV1 must be undertaken during a stable period of the disease.

Initial therapy is limited to 3 months treatment with mannitol at a dose of 400 mg twice daily.

FEV1 measurement (single test under conditions as above) and a global assessment of the patient involving the patient, the patient’s family (in the case of paediatric patients), the treating physician(s) and an additional independent member of the cystic fibrosis treatment team must be undertaken and documented following 3 months of initial therapy.

To be eligible for continued PBS-subsidised treatment with mannitol following 3 months of initial treatment:

(1) the patient must demonstrate no deterioration in FEV1 compared to baseline; AND

(2) the patient or the patient’s family (in the case of paediatric patients) must report improvement in the patient’s airway clearance; AND

(3) the treating physician(s) must report a benefit in the clinical status of the patient.

Further reassessments involving the patient, the patient’s family (in the case of paediatric patients), the treating physician(s) and an additional independent member of the cystic fibrosis treatment team must be undertaken and documented at six-monthly intervals to establish that all agree that mannitol treatment is continuing to produce worthwhile benefits. Mannitol therapy should cease if there is not general agreement of benefit as there is always the possibility of harm from unnecessary use.

Other aspects of treatment, such as physiotherapy, must be continued.

Where there is documented evidence that a patient already receiving mannitol therapy would have met the criteria for subsidy then the patient is eligible to continue treatment under the HSD program. Where such evidence is not available, patients will need to satisfy the initiation and continuation criteria as for new patients. (Four weeks is considered a suitable wash-out period.)

Authority required

Cystic fibrosis

Clinical criteria:

Patient must have initiated treatment with mannitol prior to 1 August 2012,

AND

Patient must have undergone a comprehensive assessment involving the patient’s family, the treating physician and an additional independent member of the cystic fibrosis team, which documents agreement that mannitol treatment is continuing to produce a worthwhile benefit.

Population criteria:

Patient must be 6 years of age or older.

Further reassessments are to be undertaken and documented every 6 months. Treatment with mannitol should cease if there is not agreement of benefit as there is always the possibility of harm from unnecessary use.

Note

Mannitol is not PBS-subsidised for use in combination with PBS-subsidised dornase alfa.

Note

It is highly desirable that all patients be included in the national cystic fibrosis patient database.

2008Q  MANNITOL Pack containing 280 capsules containing powder for inhalation 40 mg and 2 inhalers, 1 4 5 .. *1782.76 bronchitol XA
### HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

#### VARIOUS

##### ALL OTHER THERAPEUTIC PRODUCTS

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<td>deferasirox 125 mg tablet: dispersible, 28</td>
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<td>Exjade NV</td>
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#### Iron chelating agents

**DEFERASIROX**

*Authority required*

Chronic iron overload in patients with disorders of erythropoiesis

**Note**

Special Pricing Arrangements apply.

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<thead>
<tr>
<th>Code</th>
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<td>6500D</td>
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<td>5</td>
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<td>9600G</td>
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<td>*5652.58</td>
<td>Exjade NV</td>
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**DEFERIPRONE**

*Authority required*

Iron overload in patients with thalassaemia major who are unable to take desferrioxamine therapy

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<tr>
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<th>Name, Restriction, Manner of Administration and Form</th>
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<td>9638G</td>
<td>deferiprone 100 mg/mL oral liquid, 250 mL</td>
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<td>*1173.16</td>
<td>Ferriprox OA</td>
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<td>6416Q</td>
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#### DESFERRIOXAMINE

*Authority required*

Disorders of erythropoiesis associated with treatment-related chronic iron overload

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<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
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<td>6270B</td>
<td>desferrioxamine mesylate 2 g injection, 1 x 2 g vial</td>
<td>60</td>
<td>5</td>
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<td>*1990.96</td>
<td>a Hospira Pty Limited HH</td>
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<tr>
<td>6113R</td>
<td>desferrioxamine mesylate 500 mg injection, 10 x 500 mg vials</td>
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<td>5</td>
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<td>*2688.00</td>
<td>a Desferal 500 mg NV</td>
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</table>

**Drugs for treatment of hyperkalemia and hyperphosphatemia**

#### LANTHANUM

*Authority required*

Management of hyperphosphataemia in a patient with chronic kidney disease on dialysis whose serum phosphate is not controlled on calcium and where serum phosphate is greater than 1.6 mmol per L at the commencement of therapy.

Management includes initiation, stabilisation and review of therapy as required

**Note**

Not to be used in combination with sevelamer.

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
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<th>Brand Name and Manufacturer</th>
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<td>9637F</td>
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<tr>
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<td>*828.94</td>
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#### SEVELAMER

*Authority required*

Management of hyperphosphataemia in a patient with chronic kidney disease on dialysis whose serum phosphate is not controlled on calcium and
where serum phosphate is greater than 1.6 mmol per L at the commencement of therapy.

Management includes initiation, stabilisation and review of therapy as required

**Authority required**

Management of hyperphosphataemia in a patient with chronic kidney disease on dialysis whose serum phosphate is not controlled on calcium and where the serum calcium times phosphate product is greater than 4.0 at the commencement of therapy.

Management includes initiation, stabilisation and review of therapy as required

**Note**

Not to be used in combination with lanthanum.

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>Dispensed Price for Max. Qty $</th>
<th>Brand Name and Manufacturer</th>
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<tr>
<td>9620H</td>
<td>sevelamer hydrochloride 800 mg tablet, 180</td>
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<td>*651.56</td>
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</table>
BLOOD AND BLOOD FORMING ORGANS

ANTIHEMORRHAGICS

VITAMIN K AND OTHER HEMOSTATICS

Other systemic hemostatics

ELTROMBOPAG

Authority required

Initial (new patients)

Initial treatment, as the sole PBS-subsidised thrombopoietin receptor agonist (TRA), of severe thrombocytopenia in an adult patient with severe chronic immune (idiopathic) thrombocytopenic purpura (ITP) who is:

(1) Splenectomised and:
   (a) has had an inadequate response to, or is intolerant to, corticosteroid therapy post splenectomy; and
   (b) has had an inadequate response to, or is intolerant to, immunoglobulin therapy post splenectomy;
   OR

(2) Not splenectomised and:
   (a) has had an inadequate response, or is intolerant to, corticosteroid therapy at a dose equivalent to 0.5-2 mg/kg/day of prednisone for at least 4-6 weeks; and
   (b) has had an inadequate response, or is intolerant to, immunoglobulin therapy; and
   (c) in whom splenectomy is contraindicated for medical reasons.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of initial application:

(a) a platelet count of less than or equal to 20,000 million per L;
   OR

(b) a platelet count of 20-30,000 million per L, where the patient is experiencing significant bleeding or has a history of significant bleeding in this platelet range.

The authority application must be made in writing and must include:

(1) a completed authority prescription form,
(2) a signed patient acknowledgement,
(3) a completed Idiopathic Thrombocytopenic Purpura Initial PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)],
(4) a copy of a full blood count pathology report supporting the diagnosis of ITP, and
(5) where the application is sought on the basis of a medical contraindication to surgery, a signed and dated letter from the clinician making this assessment which includes the date upon which the patient was assessed for surgery and the clinical grounds upon which surgery is contraindicated. The full blood count must be no more than 1 month old at the time of application.

A maximum of 24 weeks of treatment with eltrombopag will be authorised under this criterion

Authority required

Initial (grandfather patients)

Initial treatment, as the sole PBS-subsidised thrombopoietin receptor agonist (TRA), of severe thrombocytopenia in an adult patient with severe chronic immune (idiopathic) thrombocytopenic purpura (ITP) who was receiving treatment with eltrombopag prior to 1 November 2011 and in whom the criteria for initial treatment can be demonstrated to have been met at the time eltrombopag was commenced.

The authority application must be made in writing and must include:

(1) a completed authority prescription form,
(2) a signed patient acknowledgement,
(3) a completed Idiopathic Thrombocytopenic Purpura Initial PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)], and
(4) where the application is sought on the basis of a medical contraindication to surgery, a signed and dated letter from the clinician making this assessment which includes the date upon which the patient was assessed for surgery and the clinical grounds upon which surgery is contraindicated.

A maximum of 24 weeks of treatment with eltrombopag will be authorised under this criterion

Authority required

Continuing therapy or re-initiation after a break in therapy

First period of PBS-subsidised continuing treatment or re-initiation of interrupted PBS-subsidised treatment, as the sole PBS-subsidised thrombopoietin receptor agonist (TRA), of severe thrombocytopenia in an adult patient with chronic immune (idiopathic) thrombocytopenic purpura (ITP) who has displayed a sustained platelet response to treatment with eltrombopag during the initial period of PBS-subsidised treatment.

For the purposes of this restriction, a sustained platelet response is defined as:
HIGHERLY SPECIALISED DRUGS PROGRAM (Public Hospital)

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>Dispensed Price for Max. Qty $</th>
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<td>Revolade GK</td>
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<td>5</td>
<td>..</td>
<td>3024.00</td>
<td>Revolade GK</td>
</tr>
</tbody>
</table>

(a) use of rescue medication (corticosteroids or immunoglobulins) on no more than one occasion during the initial period of PBS-subsidised eltrombopag,

AND either of the following:

(b) a platelet count greater than or equal to 50,000 million per L on at least four (4) occasions, each at least one week apart;

OR

(c) a platelet count greater than 30,000 million per L and which is double the baseline (pre-treatment) platelet count on at least four (4) occasions, each at least one week apart.

Applications for the first period of continuing PBS-subsidised treatment or re-initiation of interrupted treatment must be made in writing and must include:

(1) a completed authority prescription form, and

(2) a completed Idiopathic Thrombocytopenic Purpura Continuing PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)], and

(3) copies of the platelet count pathology reports (unless previously provided for patients re-initiating therapy).

The most recent platelet count must be no more than one month old at the time of application.

A maximum of 24 weeks of treatment with eltrombopag will be authorised under this criterion.

Where fewer than 5 repeats are initially requested with the authority prescription, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be made by telephone

**Authority required**

Second and subsequent applications for continuing therapy

Continuing treatment, as the sole PBS-subsidised thrombopoietin receptor agonist (TRA), of severe thrombocytopenia in an adult patient with chronic immune (idiopathic) thrombocytopenic purpura (ITP) who has previously received PBS-subsidised therapy with eltrombopag and who continues to display a response to treatment with eltrombopag.

For the purposes of this restriction, a continuing response to treatment with eltrombopag is defined as:

(a) use of rescue medication (corticosteroids or immunoglobulins) on no more than one occasion during the most recent 24 week period of PBS-subsidised treatment with eltrombopag,

AND either of the following:

(b) a platelet count greater than or equal to 50,000 million per L

OR

(c) a platelet count greater than 30,000 million per L and which is double the baseline platelet count.

Platelet counts must be no more than 1 month old at the time of application.

Authority applications for second and subsequent periods of continuing therapy may be made by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday)

**Note**

Eltrombopag is not PBS-subsidised as an alternative to splenectomy.

Any queries concerning the arrangements to prescribe eltrombopag may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authority to prescribe eltrombopag should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

Further prescribing information is on the Medicare Australia website at www.medicareaustralia.gov.au.

**Note**

Patients will be able to trial either eltrombopag and/or romiplostim within the initial 24 weeks treatment period. Patients who fail to demonstrate a response to treatment with either eltrombopag and/or romiplostim under the initial restriction will not be eligible to receive further PBS-subsidised treatment with either of these drugs.

No applications for increased repeats will be authorised.

**Note**

No applications for increased repeats will be authorised.
**Authorised required**

Initial (new patients)

Initial treatment, as the sole PBS-subsidised thrombopoietin receptor agonist (TRA), of severe thrombocytopenia in an adult patient with severe chronic immune (idiopathic) thrombocytopenic purpura (ITP) who is:

1. Splenectomised and:
   - (a) has had an inadequate response to, or is intolerant to, corticosteroid therapy post splenectomy; and
   - (b) has had an inadequate response to, or is intolerant to, immunoglobulin therapy post splenectomy;
   OR
2. Not splenectomised and:
   - (a) has had an inadequate response, or is intolerant to, corticosteroid therapy at a dose equivalent to 0.5-2 mg/kg/day of prednisone for at least 4-6 weeks; and
   - (b) has had an inadequate response, or is intolerant to, immunoglobulin therapy; and
   - (c) in whom splenectomy is contraindicated for medical reasons.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of initial application:

1. A platelet count of less than or equal to 20,000 million per L;
   OR
2. A platelet count of 20-30,000 million per L, where the patient is experiencing significant bleeding or has a history of significant bleeding in this platelet range.

The authority application must be made in writing and must include:

1. A completed authority prescription form,
2. A signed patient acknowledgement,
3. A completed Idiopathic Thrombocytopenic Purpura Initial PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].
4. A copy of a full blood count pathology report supporting the diagnosis of ITP, and
5. Where the application is sought on the basis of a medical contraindication to surgery, a signed and dated letter from the clinician making this assessment which includes the date upon which the patient was assessed for surgery and the clinical grounds upon which surgery is contraindicated.

The full blood count must be no more than 1 month old at the time of application.

At the time of the written authority application, medical practitioners should request the appropriate quantity of vials of appropriate strength to provide sufficient drug for a single treatment at a dose of 1 microgram/kg. Up to 1 repeat may be requested with the initial written application.

Subsequently during the initial period of dose titration, authority applications for a single dose and up to 1 repeat may be made by telephone by providing sufficient drug for a single treatment at a dose of 1 microgram/kg. Up to 1 repeat may be requested with the initial written application.

The dose (microgram/kg/week) must be based on the weight of the patient and dose (microgram/kg/week) to provide up to 4 weeks of treatment and up to 4 repeats may be granted, as long as the total period of treatment authorised under this restriction does not exceed 24 weeks.

Authority approval will not be given for doses of higher than 10 micrograms/kg/week

**Authority required**

Initial (grandfather patients)

Initial PBS-subsidised treatment, as the sole PBS-subsidised thrombopoietin receptor agonist (TRA), of severe thrombocytopenia in an adult patient with severe chronic immune (idiopathic) thrombocytopenic purpura (ITP) who was receiving treatment with romiplostim prior to 1 April 2011 and in whom the criteria for initial treatment can be demonstrated to have been met at the time romiplostim was commenced.

The authority application must be made in writing and must include:

1. A completed authority prescription form,
2. A signed patient acknowledgement,
3. A completed Idiopathic Thrombocytopenic Purpura Initial PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)], and
4. Where the application is sought on the basis of a medical contraindication to surgery, a signed and dated letter from the clinician making this assessment which includes the date upon which the patient was assessed for surgery and the clinical grounds upon which surgery is contraindicated.

For patients whose dose of romiplostim had been stable for at least 4 weeks at the time of the initial application for PBS-subsidy, the medical practitioner should request sufficient number of vials based on the weight of the patient and dose (microgram/kg/week) to provide up to 4 weeks of treatment. Up to a maximum of 5 repeats may be authorised.

Where the patient is in the titration phase of treatment with romiplostim, medical practitioners should request the appropriate quantity of vials of appropriate strength to provide sufficient drug for a single treatment at a dose of 1 microgram/kg. Up to 1 repeat may be requested with the initial written application.

Subsequently during the initial period of dose titration, authority applications for a single dose and up to 1 repeat may be made by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). The dose (microgram/kg/week) must be provided at the time of application.
Once a patient’s dose has been stable for a period of 4 weeks, authority approvals for sufficient vials of appropriate strength based on the weight of the patient and dose (microgram/kg/week) for up to 4 weeks of treatment and up to 4 repeats may be granted, as long as the total period of treatment authorised under this restriction does not exceed 24 weeks.

Authority approval will not be given for doses of higher than 10 micrograms/kg/week

**Authority required**

Continuing therapy or re-initiation after a break in therapy

First period of PBS-subsidised continuing treatment or re-initiation of interrupted PBS-subsidised treatment, as the sole PBS-subsidised thrombopoietin receptor agonist (TRA), of severe thrombocytopenia in an adult patient with chronic immune (idiopathic) thrombocytopenic purpura (ITP) who has displayed a sustained platelet response to treatment with romiplostim during the initial period of PBS-subsidised treatment.

For the purposes of this restriction, a sustained platelet response is defined as:

(a) use of rescue medication (corticosteroids or immunoglobulins) on no more than one occasion during the initial period of PBS-subsidised romiplostim,

AND either of the following:

(b) a platelet count greater than or equal to 50,000 million per L on at least four (4) occasions, each at least one week apart;

OR

(c) a platelet count greater than 30,000 million per L and which is double the baseline (pre-treatment) platelet count on at least four (4) occasions, each at least one week apart.

Applications for the first period of continuing PBS-subsidised treatment or re-initiation of interrupted treatment must be made in writing and must include:

(1) a completed authority prescription form, and

(2) a completed Idiopathic Thrombocytopenic Purpura Continuing PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)], and

(3) copies of the platelet count pathology reports (unless previously provided for patients re-initiating therapy).

The most recent platelet count must be no more than one month old at the time of application.

The medical practitioner should request sufficient number of vials of appropriate strength based on the weight of the patient and dose (microgram/kg/week) to provide 4 weeks of treatment. Up to a maximum of 5 repeats may be authorised.

Where fewer than 5 repeats are initially requested with the authority prescription, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be made by telephone.

Authority approval will not be given for doses of higher than 10 micrograms/kg/week

**Authority required**

Second and subsequent applications for continuing therapy

Continuing treatment, as the sole PBS-subsidised thrombopoietin receptor agonist (TRA), of severe thrombocytopenia in an adult patient with chronic immune (idiopathic) thrombocytopenic purpura (ITP) who has previously received PBS-subsidised therapy with romiplostim and who continues to display a response to treatment with romiplostim.

For the purposes of this restriction, a continuing response to treatment with romiplostim is defined as:

(a) use of rescue medication (corticosteroids or immunoglobulins) on no more than one occasion during the most recent 24 week period of PBS-subsidised treatment with romiplostim,

AND either of the following:

(b) a platelet count greater than or equal to 50,000 million per L

OR

(c) a platelet count greater than 30,000 million per L and which is double the baseline platelet count.

Platelet counts must be no more than one month old at the time of application.

Authority applications for second and subsequent periods of continuing therapy may be made by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

The medical practitioner should request sufficient number of vials of appropriate strength based on the weight of the patient and dose (microgram/kg/week) to provide 4 weeks of treatment. Up to a maximum of 5 repeats may be authorised.

Authority approval will not be given for doses of higher than 10 micrograms/kg/week

**Note**

Romiplostim is not PBS-subsidised as an alternative to splenectomy.

Any queries concerning the arrangements to prescribe romiplostim may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authority to prescribe romiplostim should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826
### Antimicrobial Agents

**EPTOPIN ALFA**

**Authority required (STREAMLINED)**

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<th>Code</th>
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<th>No. of Rpts</th>
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### Antineoplastic Agents

**EPTOPIN ALFA**

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### HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

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### METHOXY POLYETHYLENE GLYCOL-EPOETIN BETA

**Authority required (STREAMLINED)**

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<th>No. of Rpts</th>
<th>Premium $</th>
<th>Dispensed Price for Max. Qty $</th>
<th>Brand Name and Manufacturer</th>
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### Note

Epoetin lambda should only be administered by the intravenous route.
## HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

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<th>No. of Rpts</th>
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<th>Dispensed Price for Max. Qty $</th>
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CARDIOVASCULAR SYSTEM

ANTIHYPERTENSIVES

Other antihypertensives

AMBRISENTAN

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 (new patients)

Clinical criteria:

Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent,

AND

Patient must have been assessed by a physician at a designated hospital,

AND

Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditary PAH; OR

Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease,

AND

Patient must have a mean right atrial pressure of 8 mmHg or less as measured by right heart catheterisation (RHC); OR

Patient must have right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds,

AND

Patient must have failed to respond to 6 or more weeks of appropriate vasodilator treatment unless intolerance or a contraindication to such treatment exists,

AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6 Minute Walk Test (6MWT); and

(3) a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditary pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger’s physiology) are defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient’s baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments;

(2) RHC composite assessment plus 6MWT;

(3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

(1) ECHO composite assessment plus 6MWT;

(2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be...
conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Details of prior vasodilator treatment, including the dose and duration of treatment, must be provided at the time of application. Where the patient has an adverse event to a vasodilator or where vasodilator treatment is contraindicated, details of the nature of the adverse event or contraindication according to the Therapeutic Goods Administration (TGA) approved Product Information must also be provided with the application.

Response to prior vasodilator treatment is defined as follows:

For patients with 2 or more baseline tests, response to treatment is defined as 2 or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.

A maximum of 5 repeats may be requested.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term ‘PAH agents’ refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

**Note**

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

**Note**

Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 (new patients)

**Clinical criteria:**

Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent,

AND

Patient must have been assessed by a physician at a designated hospital,

AND

Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH, and a mean right atrial pressure of greater than 8 mmHg, as measured by right heart catheterisation (RHC); OR

Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH, with right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds; OR

Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease and a mean right atrial pressure greater than 8 mmHg, as measured by RHC; OR

Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease with right ventricular function assessed by ECHO where a RHC cannot be performed on clinical grounds; OR

Patient must have WHO Functional Class IV idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH; OR

Patient must have WHO Functional Class IV pulmonary arterial hypertension secondary to connective tissue disease,
The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

1. a completed authority prescription form; and
2. a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
   (i) RHC composite assessment; and
   (ii) ECHO composite assessment; and
   (iii) 6 Minute Walk Test (6MWT); and
3. a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditary pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or
(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

1. RHC plus ECHO composite assessments;
2. RHC composite assessment plus 6MWT;
3. RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

1. ECHO composite assessment plus 6MWT;
2. ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats may be requested.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Note

Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

Authority required

Pulmonary arterial hypertension (PAH)
Treatment Phase: Initial 3 (change or re-commencement of therapy for all patients)

Clinical criteria:

Patient must have idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease and must wish to re-commence PBS-subsidised therapy with this agent after a break in therapy and must have demonstrated a response to their most recent course of PBS-subsidised treatment with this agent; OR

Patient must have idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease and whose most recent course of PBS-subsidised treatment was with a PAH agent other than this agent,

AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form; and

(3) the results of the patient’s response to treatment with their last course of PBS-subsidised PAH agent.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats may be requested.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with the drug they are ceasing.

The term ‘PAH agents’ refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Swapping between PAH agents:

Patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment with 1 of these 7 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent’s restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. New baselines may be submitted where the patient has failed to respond to their current treatment.

Eligible patients may only swap between PAH agents if they have not failed prior PBS-subsidised treatment with that agent.

For eligible patients, applications to swap between the 7 PAH agents must be made under the relevant initial treatment restriction. Patients should be assessed for response to the treatment they are ceasing at the time the application to swap therapy is being made. Patients who fail to demonstrate a response or for whom no assessment results are submitted with the application to swap therapy may not re-commence PBS-subsidised treatment with the drug they are ceasing.

Note

Applications for patients who wish to swap to an alternate PAH agent should be accompanied by the previously approved authority prescription, or remaining repeats, for the treatment the patient is ceasing.

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826
Note
Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

Authority required
Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 or Initial 2 (new patients) or Initial 3 (change or re-commencement of therapy for all patients) or Continuing treatment (all patients) – balance of supply

Clinical criteria:
Patient must have received insufficient therapy with this agent under the Initial 1 (new patients) restriction to complete a maximum of six months of treatment; OR
Patient must have received insufficient therapy with this agent under the Initial 2 (new patients) restriction to complete a maximum of six months of treatment; OR
Patient must have received insufficient therapy with this agent under the Initial 3 (change or re-commencement of therapy for all patients) restriction to complete a maximum of six months of treatment; OR
Patient must have received insufficient therapy with this agent under the Continuing treatment (all patients) restriction to complete a maximum of six months of treatment;

AND

The treatment must be the sole PBS-subsidised PAH agent for this condition,

AND

The treatment must provide no more than the balance of up to six months treatment available under the above restrictions.

Note
Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authorisation under this criterion should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Authority required
Pulmonary arterial hypertension (PAH)

Treatment Phase: Continuing treatment (all patients)

Clinical criteria:
Patient must have received approval for initial PBS-subsidised treatment with this agent,

AND

Patient must have been assessed by a physician from a designated hospital to have achieved a response to their most recent course of treatment with this agent,

AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and
(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
   (i) RHC composite assessment; and
   (ii) ECHO composite assessment; and
   (iii) 6 Minute Walk Test (6MWT).

Test requirements to establish response to treatment for continuation of treatment are as follows:
The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:
(1) RHC plus ECHO composite assessments plus 6MWT;
(2) RHC plus ECHO composite assessments;
(3) RHC composite assessment plus 6MWT;
(4) ECHO composite assessment plus 6MWT;
(5) RHC composite assessment only;
The results of the same tests as conducted at baseline should be provided with each written continuing treatment application (i.e., every 6 months), except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application.

The test results provided with the application for continuing treatment must be no more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

The assessment of the patient’s response to the first and subsequent 6 month courses of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Applications for continuing treatment with a PAH agent should be made prior to the completion of the 6 month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Caution

This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 3 months following cessation of therapy.

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

Note

Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

5608E ambrisentan 10 mg tablet, 30 1 .. .. 2876.47 Volibris GK

5607D ambrisentan 5 mg tablet, 30 1 .. .. 2876.47 Volibris GK

BOSENTAN

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 (new patients)

Clinical criteria:

Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent,

AND

Patient must have been assessed by a physician at a designated hospital.

842
Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH; OR

AND

Patient must have a mean right atrial pressure of 8 mmHg or less as measured by right heart catheterisation (RHC); OR

AND

Patient must have right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds,

AND

Patient must have failed to respond to 6 or more weeks of appropriate vasodilator treatment unless intolerance or a contraindication to such treatment exists,

AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) two completed authority prescription forms; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6 Minute Walk Test (6MWT); and

(3) a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditable pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments;

(2) RHC composite assessment plus 6MWT;

(3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

(1) ECHO composite assessment plus 6MWT;

(2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Details of prior vasodilator treatment, including the dose and duration of treatment, must be provided at the time of application. Where the patient has an adverse event to a vasodilator or where vasodilator treatment is contraindicated details of the nature of the adverse event or contraindication according to the Therapeutic Goods Administration (TGA) approved Product Information must also be provided with the application.

Response to prior vasodilator treatment is defined as follows:

For patients with 2 or more baseline tests, response to treatment is defined as 2 or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

Approvals for the first authority prescription will be limited to 1 month of therapy with the 62.5 mg strength tablet, with the quantity approved...
The second authority prescription may be written for either the 62.5 mg tablet or the 125 mg tablet strengths. Approvals for the second authority prescription will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term ‘PAH agents’ refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

**Note**

Where the 62.5 mg tablet strength is required for the second authority prescription, please contact the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) for further advice.

The approved second authority prescription will be returned to the prescriber by the Department of Human Services two weeks after the date of the approval of the first authority prescription, to allow for the uninterrupted completion of the six months initial treatment course. The Department of Human Services will contact prescribers prior to dispatch of the second authority prescription to confirm the tablet strength required for the patient.

**Note**

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

**Note**

Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 (new patients)

**Clinical criteria:**

Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent,

AND

Patient must have been assessed by a physician at a designated hospital,

AND

Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH, and a mean right atrial pressure of greater than 8 mmHg, as measured by right heart catheterisation (RHC); OR

Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH, with right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds; OR

Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease and a mean right atrial pressure greater than 8 mmHg, as measured by RHC; OR

Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease with right ventricular function assessed by ECHO where a RHC cannot be performed on clinical grounds; OR

Patient must have WHO Functional Class IV idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH; OR

Patient must have WHO Functional Class IV pulmonary arterial hypertension secondary to connective tissue disease; OR

Patient must have WHO Functional Class III or IV pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger’s physiology).

AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) two completed authority prescription forms; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditable pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger’s physiology) are defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or
(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient’s baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments;
(2) RHC composite assessment plus 6MWT;
(3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

(1) ECHO composite assessment plus 6MWT;
(2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Approvals for the first authority prescription will be limited to 1 month of therapy with the 62.5 mg strength tablet, with the quantity approved based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information. No repeats will be authorised for this prescription.

The second authority prescription may be written for either the 62.5 mg tablet or the 125 mg tablet strengths. Approvals for the second authority prescription will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats.

The term ‘PAH agents’ refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Note
Where the 62.5 mg tablet strength is required for the second authority prescription, please contact the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) for further advice.

The approved second authority prescription will be returned to the prescriber by the Department of Human Services two weeks after the date of the approval of the first authority prescription, to allow for the uninterrupted completion of the six months initial treatment course. The Department of Human Services will contact prescribers prior to dispatch of the second authority prescription to confirm the tablet strength required for the patient.

Note
Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
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Reply Paid 9826
GPO Box 9826
HOBART TAS 7001
The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

Swapping between PAH agents:

Patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment with 1 of these 7 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent’s restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. New baselines may be submitted where the patient has failed to respond to their current treatment.

Eligible patients may only swap between PAH agents if they have not failed prior PBS-subsidised treatment with that agent.

For eligible patients, applications to swap between the 7 PAH agents must be made under the relevant initial treatment restriction. Patients should be assessed for response to the treatment they are ceasing at the time the application to swap therapy is being made. Patients who fail to demonstrate a response or for whom no assessment results are submitted with the application to swap therapy may not re-commence PBS-subsidised treatment with the drug they are ceasing.

Note

Where the 62.5 mg tablet strength is required for the second authority prescription, please contact the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) for further advice.

The approved second authority prescription will be returned to the prescriber by the Department of Human Services two weeks after the date of the approval of the first authority prescription, to allow for the uninterrupted completion of the six months initial treatment course. The Department of
Human Services will contact prescribers prior to dispatch of the second authority prescription to confirm the tablet strength required for the patient.

**Note**
Applications for patients who wish to swap to an alternate PAH agent should be accompanied by the previously approved authority prescription, or remaining repeats, for the treatment the patient is ceasing.

**Note**
Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
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GPO Box 9826
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**Note**
Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

**Authority required**
Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 or Initial 2 (new patients) or Initial 3 (change or re-commencement of therapy for all patients) or Continuing treatment (all patients) – balance of supply

**Clinical criteria:**
Patient must have received insufficient therapy with this agent under the Initial 1 (new patients) restriction to complete a maximum of six months of treatment; OR
Patient must have received insufficient therapy with this agent under the Initial 2 (new patients) restriction to complete a maximum of six months of treatment; OR
Patient must have received insufficient therapy with this agent under the Initial 3 (change or re-commencement of therapy for all patients) restriction to complete a maximum of six months of treatment; OR
Patient must have received insufficient therapy with this agent under the Continuing treatment (all patients) restriction to complete a maximum of six months of treatment,

AND

The treatment must be the sole PBS-subsidised PAH agent for this condition,

AND

The treatment must provide no more than the balance of up to six months treatment available under the above restrictions.

**Note**
Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authorisation under this criterion should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

**Authority required**
Pulmonary arterial hypertension (PAH)

Treatment Phase: Continuing treatment (all patients)

**Clinical criteria:**
Patient must have received approval for initial PBS-subsidised treatment with this agent,

AND

Patient must have been assessed by a physician from a designated hospital to have achieved a response to their most recent course of treatment with this agent,

AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
(i) RHC composite assessment; and
(ii) ECHO composite assessment; and
(iii) 6 Minute Walk Test (6MWT).

Test requirements to establish response to treatment for continuation of treatment are as follows:

The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:
(1) RHC plus ECHO composite assessments plus 6MWT;
(2) RHC plus ECHO composite assessments;
(3) RHC composite assessment plus 6MWT;
(4) ECHO composite assessment plus 6MWT;
(5) RHC composite assessment only;
(6) ECHO composite assessment only.

The results of the same tests as conducted at baseline should be provided with each written continuing treatment application (i.e., every 6 months), except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application.

The test results provided with the application for continuing treatment must be no more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:
For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.
For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.
For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.
For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

The assessment of the patient's response to the first and subsequent 6 month courses of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Applications for continuing treatment with a PAH agent should be made prior to the completion of the 6 month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Caution
This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 3 months following cessation of therapy.

Note
Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001
Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

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<th>No. of Rpts</th>
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**BOSENTAN**

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 (new patients)

**Clinical criteria:**

Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, AND

Patient must have been assessed by a physician at a designated hospital, AND

Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH; OR

Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease, AND

Patient must have a mean right atrial pressure of 8 mmHg or less as measured by right heart catheterisation (RHC); OR

Patient must have right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds, AND

Patient must have failed to respond to 6 or more weeks of appropriate vasodilator treatment unless intolerance or a contraindication to such treatment exists, AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

1. two completed authority prescription forms; and
2. a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
   i. RHC composite assessment; and
   ii. ECHO composite assessment; and
   iii. 6 Minute Walk Test (6MWT); and
3. a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditable pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient’s baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

1. RHC plus ECHO composite assessments;
2. RHC composite assessment plus 6MWT;
3. RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

1. ECHO composite assessment plus 6MWT;
2. ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Details of prior vasodilator treatment, including the dose and duration of treatment, must be provided at the time of application. Where the patient
 Response to prior vasodilator treatment is defined as follows:

- For patients with 2 or more baseline tests, response to treatment is defined as 2 or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.
- For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.
- For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.
- For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

Approvals for the first authority prescription will be limited to 1 month of therapy with the 62.5 mg strength tablet, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information. No repeats will be authorised for this prescription.

The second authority prescription may be written for either the 62.5 mg tablet or the 125 mg tablet strengths. Approvals for the second authority prescription will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Note
Where the 62.5 mg tablet strength is required for the second authority prescription, please contact the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) for further advice.

The approved second authority prescription will be returned to the prescriber by the Department of Human Services two weeks after the date of the approval of the first authority prescription, to allow for the uninterrupted completion of the six months initial treatment course. The Department of Human Services will contact prescribers prior to dispatch of the second authority prescription to confirm the tablet strength required for the patient.

Note
Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Note
Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

Authority required
Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 (new patients)

Clinical criteria:
- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent,

AND
- Patient must have been assessed by a physician at a designated hospital,

AND
- Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH, and a mean right atrial pressure of greater than 8 mmHg, as measured by right heart catheterisation (RHC); OR
- Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH, with right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds; OR
- Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease and a mean right atrial pressure greater than 8 mmHg, as measured by RHC; OR
- Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease with right ventricular function...
### HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

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<th>Brand Name and Manufacturer</th>
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- Assess by ECHO where a RHC cannot be performed on clinical grounds; OR
- Patient must have WHO Functional Class IV idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or heritable PAH; OR
- Patient must have WHO Functional Class IV pulmonary arterial hypertension secondary to connective tissue disease; OR
- Patient must have WHO Functional Class III or IV pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger’s physiology), AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:
1. Two completed authority prescription forms; and
2. A completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
   i. RHC composite assessment; and
   ii. ECHO composite assessment; and
   iii. 6 Minute Walk Test (6MWT); and
3. A signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, heritable pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger’s physiology) are defined as follows:

(i) Mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or
(ii) Where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

- The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient’s baseline measurements.

- Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:
  1. RHC plus ECHO composite assessments;
  2. RHC composite assessment plus 6MWT;
  3. RHC composite assessment only.

- In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:
  1. ECHO composite assessment plus 6MWT;
  2. ECHO composite assessment only.

- Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Approvals for the first authority prescription will be limited to 1 month of therapy with the 62.5 mg strength tablet, with the quantity approved based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information. No repeats will be authorised for this prescription.

The second authority prescription may be written for either the 62.5 mg tablet or the 125 mg tablet strengths. Approvals for the second authority prescription will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats.

- The term ‘PAH agents’ refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

- Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

**Note**

Where the 62.5 mg tablet strength is required for the second authority prescription, please contact the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) for further advice.

The approved second authority prescription will be returned to the prescriber by the Department of Human Services two weeks after the date of the approval of the first authority prescription, to allow for the uninterrupted completion of the six months initial treatment course. The Department of Human Services will contact prescribers prior to dispatch of the second authority prescription to confirm the tablet strength required for the patient.
Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au.

Applications for authority to prescribe should be forwarded to:

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Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Note
Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

**Authority required**

**Pulmonary arterial hypertension (PAH)**

**Treatment Phase: Initial 3** (change or re-commencement of therapy for all patients)

**Clinical criteria:**

Patient must have idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease or PAH associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger’s physiology) and must wish to re-commence PBS-subsidised therapy with this agent after a break in therapy and must have demonstrated a response to their most recent course of PBS-subsidised treatment with this agent; OR

Patient must have idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease or PAH associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger’s physiology) and whose most recent course of PBS-subsidised treatment was with a PAH agent other than this agent, AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

1. two completed authority prescription forms; and
2. a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form; and
3. the results of the patient’s response to treatment with their last course of PBS-subsidised PAH agent.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

Approvals for the first authority prescription will be limited to 1 month of therapy with the 62.5 mg strength tablet, with the quantity approved based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information. No repeats will be authorised for this prescription.

The second authority prescription may be written for either the 62.5 mg tablet or the 125 mg tablet strengths. Approvals for the second authority prescription will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term ‘PAH agents’ refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Swapping between PAH agents:

Patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment with 1 of these 7 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that
patients may commence treatment with the alternate agent, subject to that agent’s restriction, irrespective of the severity of their disease at the
time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. New baselines may be
submitted where the patient has failed to respond to their current treatment.

Eligible patients may only swap between PAH agents if they have not failed prior PBS-subsidised treatment with that agent.

For eligible patients, applications to swap between the 7 PAH agents must be made under the relevant initial treatment restriction. Patients should
be assessed for response to the treatment they are ceasing at the time the application to swap therapy is being made. Patients who fail to
demonstrate a response or for whom no assessment results are submitted with the application to swap therapy may not re-commence PBS-
subsidised treatment with the drug they are ceasing.

Note
Where the 62.5 mg tablet strength is required for the second authority prescription, please contact the Department of Human Services on 1800 700 270
(hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) for further advice.

The approved second authority prescription will be returned to the prescriber by the Department of Human Services two weeks after the date of the
approval of the first authority prescription, to allow for the uninterrupted completion of the six months initial treatment course. The Department of
Human Services will contact prescribers prior to dispatch of the second authority prescription to confirm the tablet strength required for the
patient.

Note
Applications for patients who wish to swap to an alternate PAH agent should be accompanied by the previously approved authority prescription, or
remaining repeats, for the treatment the patient is ceasing.

Note
Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation
8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of
Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Note
Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

Authority required
Pulmonary arterial hypertension (PAH)
Treatment Phase: Initial 1 or Initial 2 (new patients) or Initial 3 (change or re-commencement of therapy for all patients) or Continuing treatment (all
patients) - balance of supply

Clinical criteria:
Patient must have received insufficient therapy with this agent under the Initial 1 (new patients) restriction to complete a maximum of six months of
treatment; OR
Patient must have received insufficient therapy with this agent under the Initial 2 (new patients) restriction to complete a maximum of six months of
treatment; OR
Patient must have received insufficient therapy with this agent under the Initial 3 (change or re-commencement of therapy for all patients)
restriction to complete a maximum of six months of treatment; OR
Patient must have received insufficient therapy with this agent under the Continuing treatment (all patients) restriction to complete a maximum of
six months of treatment,

AND
The treatment must be the sole PBS-subsidised PAH agent for this condition,

AND
The treatment must provide no more than the balance of up to six months treatment available under the above restrictions.

Note
Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270
(hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authorisation under this criterion should be forwarded to:

Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001
HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Continuing treatment (all patients)

**Clinical criteria:**

Patient must have received approval for initial PBS-subsidised treatment with this agent,

AND

Patient must have been assessed by a physician from a designated hospital to have achieved a response to their most recent course of treatment with this agent.

AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

1. a completed authority prescription form; and
2. a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
   1. RHC composite assessment; and
   2. ECHO composite assessment; and
   3. 6 Minute Walk Test (6MWT).

**Test requirements to establish response to treatment for continuation of treatment are as follows:**

The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:

1. RHC plus ECHO composite assessments plus 6MWT;
2. RHC plus ECHO composite assessments;
3. RHC composite assessment plus 6MWT;
4. ECHO composite assessment plus 6MWT;
5. RHC composite assessment only;
6. ECHO composite assessment only.

The results of the same tests as conducted at baseline should be provided with each written continuing treatment application (i.e., every 6 months), except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application.

The test results provided with the application for continuing treatment must be no more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

The assessment of the patient’s response to the first and subsequent 6 month courses of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Applications for continuing treatment with a PAH agent should be made prior to the completion of the 6 month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

**Note**

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of
**HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)**

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty</th>
<th>No. of Rpts</th>
<th>Premium Qty</th>
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**EPOPROSTENOL**

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 (new patients)

Clinical criteria:

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent,

- Patient must have been assessed by a physician at a designated hospital,

- Patient must have WHO Functional Class IV idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH; OR

- Patient must have WHO Functional Class IV pulmonary arterial hypertension secondary to connective tissue disease,

- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

1. a completed authority prescription form; and

2. a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

Note

Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Cessation of treatment (all patients)

Clinical criteria:

- Patient must have received approval for initial PBS-subsidised treatment with this agent,

- Patient must have not responded to prior PBS-subsidised therapy with this agent,

- The treatment must be for the purpose of gradual dose reduction prior to ceasing therapy,

- The treatment must be the sole PBS-subsidised PAH agent for this condition.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment. Treatment beyond 1 month will not be approved.

**Caution**

This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 3 months following cessation of therapy.

Note

Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authorisation under this criterion should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

**Note**

Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.
Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditable pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger’s physiology) are defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient’s baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

1. RHC plus ECHO composite assessments;
2. RHC composite assessment plus 6MWT;
3. RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

1. ECHO composite assessment plus 6MWT;
2. ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats may be requested.

 Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term ‘PAH agents’ refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

**Note**

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

**Note**

Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

**Note**

Pharmaceutical benefits that have the form epoprostenol sodium powder for I.V. infusion 1.5 mg (base) infusion administration set and pharmaceutical benefits that have the form epoprostenol 1.5 mg injection vial are equivalent for the purposes of substitution.

**Note**

Pharmaceutical benefits that have the form epoprostenol sodium powder for I.V. infusion 500 micrograms (base) infusion administration set and pharmaceutical benefits that have the form epoprostenol 500 microgram injection vial are equivalent for the purposes of substitution.

**Authority required**
HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 (change or re-commencement of therapy for all patients)

Clinical criteria:

Patient must have idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease and must wish to re-commence PBS-subsidised therapy with this agent after a break in therapy and must have demonstrated a response to their most recent course of PBS-subsidised treatment with this agent; OR

Patient must have WHO Functional Class IV idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease and must have received prior treatment with a PBS-subsidised PAH agent other than this agent; OR

Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease and must have failed to respond to a prior PBS-subsidised PAH agent,

AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

1. a completed authority prescription form; and
2. a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form; and
3. the results of the patient’s response to treatment with their last course of PBS-subsidised PAH agent; and
4. for WHO Functional Class III patients, where this is the first application for this agent, assessment details of the PBS-subsidised PAH agent they have failed to respond to.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats may be requested.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Swapping between PAH agents:

Patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment with 1 of these 7 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent’s restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. New baselines may be submitted where the patient has failed to respond to their current treatment.

Eligible patients may only swap between PAH agents if they have not failed prior PBS-subsidised treatment with that agent.

For eligible patients, applications to swap between the 7 PAH agents must be made under the relevant initial treatment restriction. Patients should be assessed for response to the treatment they are ceasing at the time the application to swap therapy is being made. Patients who fail to demonstrate a response or for whom no assessment results are submitted with the application to swap therapy may not re-commence PBS-subsidised treatment with the drug they are ceasing.

Note

Applications for patients who wish to swap to an alternate PAH agent should be accompanied by the previously approved authority prescription, or remaining repeats, for the treatment the patient is ceasing.

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Note
Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

Note
Pharmaceutical benefits that have the form epoprostenol sodium powder for I.V. infusion 1.5 mg (base) infusion administration set and pharmaceutical benefits that have the form epoprostenol 1.5 mg injection vial are equivalent for the purposes of substitution.

Note
Pharmaceutical benefits that have the form epoprostenol sodium powder for I.V. infusion 500 micrograms (base) infusion administration set and pharmaceutical benefits that have the form epoprostenol 500 microgram injection vial are equivalent for the purposes of substitution.

Authority required
Pulmonary arterial hypertension (PAH)
Treatment Phase: Initial 1 (new patients) or Initial 2 (change or re-commencement of therapy for all patients) or Continuing treatment (all patients) - balance of supply

Clinical criteria:
Patient must have received insufficient therapy with this agent under the Initial 1 (new patients) restriction to complete a maximum of six months of treatment; OR
Patient must have received insufficient therapy with this agent under the Initial 2 (change or re-commencement of therapy for all patients) restriction to complete a maximum of six months of treatment; OR
Patient must have received insufficient therapy with this agent under the Continuing treatment (all patients) restriction to complete a maximum of six months of treatment,

AND
The treatment must be the sole PBS-subsidised PAH agent for this condition,

AND
The treatment must provide no more than the balance of up to six months treatment available under the above restrictions.

Note
Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written applications for authorisation under this criterion should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Note
Pharmaceutical benefits that have the form epoprostenol sodium powder for I.V. infusion 1.5 mg (base) infusion administration set and pharmaceutical benefits that have the form epoprostenol 1.5 mg injection vial are equivalent for the purposes of substitution.

Note
Pharmaceutical benefits that have the form epoprostenol sodium powder for I.V. infusion 500 micrograms (base) infusion administration set and pharmaceutical benefits that have the form epoprostenol 500 microgram injection vial are equivalent for the purposes of substitution.

Authority required
Pulmonary arterial hypertension (PAH)
Treatment Phase: Continuing treatment (all patients)

Clinical criteria:
Patient must have received approval for initial PBS-subsidised treatment with this agent,

AND
Patient must have been assessed by a physician from a designated hospital to have achieved a response to their most recent course of treatment with this agent,

AND
The treatment must be the sole PBS-subsidised PAH agent for this condition.
Applications for authorisation must be in writing and must include:
HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

<table>
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<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>Qty $</th>
<th>Brand Name and Manufacturer</th>
</tr>
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</table>

(1) a completed authority prescription form; and
(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
   (i) RHC composite assessment; and
   (ii) ECHO composite assessment; and
   (iii) 6 Minute Walk Test (6MWT).

Test requirements to establish response to treatment for continuation of treatment are as follows:

The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:
(1) RHC plus ECHO composite assessments plus 6MWT;
(2) RHC plus ECHO composite assessments;
(3) RHC composite assessment plus 6MWT;
(4) ECHO composite assessment plus 6MWT;
(5) RHC composite assessment only;
(6) ECHO composite assessment only.

The results of the same tests as conducted at baseline should be provided with each written continuing treatment application (i.e., every 6 months), except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application.

The test results provided with the application for continuing treatment must be no more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

The assessment of the patient’s response to the first and subsequent 6 month courses of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Applications for continuing treatment with a PAH agent should be made prior to the completion of the 6 month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term ‘PAH agents’ refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Note

Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

Note

Pharmaceutical benefits that have the form epoprostenol sodium powder for I.V. infusion 1.5 mg (base) infusion administration set and
Note
Pharmaceutical benefits that have the form epoprostenol 1.5 mg injection vial are equivalent for the purposes of substitution.

Pharmaceutical benefits that have the form epoprostenol sodium powder for I.V. infusion 500 micrograms (base) infusion administration set and pharmaceutical benefits that have the form epoprostenol 500 microgram injection vial are equivalent for the purposes of substitution.

5035B  EPOPROSTENOL SODIUM Powder for I.V. infusion 1.5 mg (base) infusion administration set, 1 pack
Max. Qty (Packs) No. of Rpts Premium $ Dispensed Price for Max. Qty Premium $ Brand Name and Manufacturer
1 .. .. 66.55 a Flolan Kit GK

5030R  EPOPROSTENOL SODIUM Powder for I.V. infusion 500 micrograms (base) infusion administration set, 1 pack
Max. Qty (Packs) No. of Rpts Premium $ Dispensed Price for Max. Qty Premium $ Brand Name and Manufacturer
1 .. .. 33.28 a Flolan Kit GK

10117L  epoprostenol 1.5 mg injection, 1 x 1.5 mg vial
Max. Qty (Packs) No. of Rpts Premium $ Dispensed Price for Max. Qty Premium $ Brand Name and Manufacturer
1 .. .. 66.55 a Veletri AT

10130E  epoprostenol 500 microgram injection, 1 x 500 microgram vial
Max. Qty (Packs) No. of Rpts Premium $ Dispensed Price for Max. Qty Premium $ Brand Name and Manufacturer
1 .. .. 33.28 a Veletri AT

ILOPROST

Authority required
Pulmonary arterial hypertension (PAH)
Treatment Phase: Initial 1 (new patients)

Clinical criteria:
Patient must not have received prior PBS-subsidised treatment with this agent,
AND
Patient must have been assessed by a physician at a designated hospital,
AND
Patient must have WHO Functional Class III drug-induced PAH,
AND
Patient must have a mean right atrial pressure of 8 mmHg or less as measured by right heart catheterisation (RHC); OR
Patient must have right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds,
AND
Patient must have failed to respond to 6 or more weeks of appropriate vasodilator treatment unless intolerance or a contraindication to such treatment exists,
AND
The treatment must be the sole PBS-subsidised PAH agent for this condition.
Applications for authorisation must be in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
   (i) RHC composite assessment; and
   (ii) ECHO composite assessment; and
   (iii) 6 Minute Walk Test (6MWT); and
(3) a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditable pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:
(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or
(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:
The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.
Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:
(1) RHC plus ECHO composite assessments;
(2) RHC composite assessment plus 6MWT;
(3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the
following test combinations, which are listed in descending order of preference:

(1) ECHO composite assessment plus 6MWT;

(2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Details of prior vasodilator treatment, including the dose and duration of treatment, must be provided at the time of application. Where the patient has an adverse event to a vasodilator or where vasodilator treatment is contraindicated, details of the nature of the adverse event or contraindication according to the Therapeutic Goods Administration (TGA) approved Product Information must also be provided with the application.

Response to prior vasodilator treatment is defined as follows:

For patients with 2 or more baseline tests, response to treatment is defined as 2 or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.

A maximum of 5 repeats may be requested.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

**Note**

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

**Note**

Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

**Note**

Special Pricing Arrangements apply.

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 (new patients)

**Clinical criteria:**

Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent,

AND

Patient must have been assessed by a physician at a designated hospital,

AND

Patient must have WHO Functional Class III drug-induced PAH and a mean right atrial pressure greater than 8 mmHg, as measured by right heart catheterisation (RHC); OR

Patient must have WHO Functional Class III drug-induced PAH with right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds; OR

Patient must have WHO Functional Class IV idiopathic pulmonary arterial hypertension (IPAH), or anorexigen-induced PAH or hereditable PAH; OR
**Patient must have WHO Functional Class IV pulmonary arterial hypertension secondary to connective tissue disease; OR**

**Patient must have WHO Functional Class IV drug-induced PAH,**

**AND**

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

1. a completed authority prescription form; and
2. a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
   i. RHC composite assessment; and
   ii. ECHO composite assessment; and
   iii. 6 Minute Walk Test (6MWT); and
3. a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditary pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger’s physiology) are defined as follows:

1. mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or
2. where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient’s baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

1. RHC plus ECHO composite assessments;
2. RHC composite assessment plus 6MWT;
3. RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

1. ECHO composite assessment plus 6MWT;
2. ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats may be requested.

The term ‘PAH agents’ refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

**Note**

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

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For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

PAH agents are not PBS-subsidised.

PAH agents are the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

1. a completed authority prescription form; and
2. a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form; and
3. the results of the patient’s response to treatment with their last course of PBS-subsidised PAH agent; and
4. for WHO Functional Class III patients, where this is the first application for this agent, assessment details of the PBS-subsidised PAH agent they have failed to respond to.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The results provided must not be more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years or 18 years or over, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats may be requested.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term ‘PAH agents’ refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Swapping between PAH agents:

Patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment with 1 of these 7 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent’s restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. New baselines may be submitted where the patient has failed to respond to their most recent course of PBS-subsidised treatment with this agent.

Eligible patients may only swap between PAH agents if they have not failed prior PBS-subsidised treatment with that agent.

For eligible patients, applications to swap between the 7 PAH agents must be made under the relevant initial treatment restriction. Patients should be assessed for response to the treatment they are ceasing at the time the application to swap therapy is made. Patients who fail to demonstrate a response or for whom no assessment results are submitted with the application to swap therapy may not re-commence PBS-subsidised treatment with the drug they are ceasing.

**Note**

Applications for patients who wish to swap to an alternate PAH agent should be accompanied by the previously approved authority prescription, or remaining repeats, for the treatment the patient is ceasing.
### Pulmonary arterial hypertension (PAH)

**Treatment Phase:** Initial 1 or Initial 2 (new patients) or Initial 3 (change or re-commencement of therapy for all patients) or Continuing treatment (all patients) – balance of supply

**Clinical criteria:**
- Patient must have received insufficient therapy with this agent under the Initial 1 (new patients) restriction to complete a maximum of six months of treatment; OR
- Patient must have received insufficient therapy with this agent under the Initial 2 (new patients) restriction to complete a maximum of six months of treatment; OR
- Patient must have received insufficient therapy with this agent under the Initial 3 (change or re-commencement of therapy for all patients) restriction to complete a maximum of six months of treatment; OR
- Patient must have received insufficient therapy with this agent under the Continuing treatment (all patients) restriction to complete a maximum of six months of treatment,

**AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition,

**AND**
- The treatment must provide no more than the balance of up to six months treatment available under the above restrictions.

**Note**
- Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
- Written applications for authorisation under this criterion should be forwarded to:
  - Department of Human Services
  - Prior Written Approval of Complex Drugs
  - Reply Paid 9826
  - GPO Box 9826
  - HOBART TAS 7001

**Note**
- Special Pricing Arrangements apply.
[1] a completed authority prescription form; and
[2] a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
(i) RHC composite assessment; and
(ii) ECHO composite assessment; and
(iii) 6 Minute Walk Test (6MWT).

Test requirements to establish response to treatment for continuation of treatment are as follows:
The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:
(1) RHC plus ECHO composite assessments plus 6MWT;
(2) RHC plus ECHO composite assessments;
(3) RHC composite assessment plus 6MWT;
(4) ECHO composite assessment plus 6MWT;
(5) RHC composite assessment only;
(6) ECHO composite assessment only.

The results of the same tests as conducted at baseline should be provided with each written continuing treatment application (i.e., every 6 months), except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application.

The test results provided with the application for continuing treatment must be no more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:
For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.
For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.
For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.
For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.
The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.
The assessment of the patient's response to the first and subsequent 6 month courses of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.
Applications for continuing treatment with a PAH agent should be made prior to the completion of the 6 month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician.
Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.
The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Note
Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Note
Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

Note
Special Pricing Arrangements apply.
MACITENTAN

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 (new patients)

Clinical criteria:

Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent,

AND

Patient must have been assessed by a physician at a designated hospital,

AND

Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (IPAH) or anorexigen-induced PAH or hereditary PAH; OR

Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease,

AND

Patient must have a mean right atrial pressure of 8 mmHg or less as measured by right heart catheterisation (RHC); OR

Patient must have right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds,

AND

Patient must have failed to respond to 6 or more weeks of appropriate vasodilator treatment unless intolerance or a contraindication to such treatment exists,

AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6 Minute Walk Test (6MWT); and

(3) a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditary pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger’s physiology) are defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient’s baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments;

(2) RHC composite assessment plus 6MWT;

(3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

(1) ECHO composite assessment plus 6MWT;

(2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Details of prior vasodilator treatment, including the dose and duration of treatment, must be provided at the time of application. Where the patient has an adverse event to a vasodilator or where vasodilator treatment is contraindicated, details of the nature of the adverse event or contraindication according to the Therapeutic Goods Administration (TGA) approved Product Information must also be provided with the
### HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

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### Response to prior vasodilator treatment is defined as follows:
- For patients with 2 or more baseline tests, response to treatment is defined as 2 or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.
- For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.
- For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.
- For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.

A maximum of 5 repeats may be requested.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

### Note
Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

### Authority required
Pulmonary arterial hypertension (PAH)

**Treatment Phase: Initial 2 (new patients)**

**Clinical criteria:**

Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent,

**AND**

Patient must have been assessed by a physician at a designated hospital,

**AND**

Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH, and a mean right atrial pressure of greater than 8 mmHg, as measured by right heart catheterisation (RHC); OR

Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH, with right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds; OR

Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease and a mean right atrial pressure greater than 8 mmHg, as measured by RHC; OR

Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease with right ventricular function assessed by ECHO where a RHC cannot be performed on clinical grounds; OR

Patient must have WHO Functional Class IV idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH; OR

Patient must have WHO Functional Class IV pulmonary arterial hypertension secondary to connective tissue disease; OR

Patient must have WHO Functional Class III or IV pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger’s physiology),

**AND**

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:
(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three
tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6 Minute Walk Test (6MWT); and

(3) a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditable pulmonary arterial hypertension,
drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or
pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger’s physiology) are defined as
follows:

(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by
echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter
(RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient’s
baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending
order, for the purposes of initiation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments;

(2) RHC composite assessment plus 6MWT;

(3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the
following test combinations, which are listed in descending order of preference:

(1) ECHO composite assessment plus 6MWT;

(2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be
conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in
the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats may be requested.

The term ‘PAH agents’ refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and
macitentan.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease
PBS-subsidised therapy with this agent.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue
disease, where the total lung capacity is less than 70% of predicted.

**Note**

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation
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Applications for authority to prescribe should be forwarded to:

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**Note**

Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 3 (change or re-commencement of therapy for all patients)

Clinical criteria:
The term ‘PAH agents’ refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and PBS-subsidised therapy with this agent. Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease the Therapeutic Goods Administration (TGA) approved Product Information. A maximum of 5 repeats may be requested.

Patient must have idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease or PAH associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger’s physiology) and whose most recent course of PBS-subsidised treatment was with a PAH agent other than this agent.

AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form; and

(3) the results of the patient’s response to treatment with their last course of PBS-subsidised PAH agent.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats may be requested.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term ‘PAH agents’ refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Swapping between PAH agents:

Patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment with 1 of these 7 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent’s restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. New baselines may be submitted where the patient has failed to respond to their current treatment.

Eligible patients may only swap between PAH agents if they have not failed prior PBS-subsidised treatment with that agent.

For eligible patients, applications to swap between the 7 PAH agents must be made under the relevant initial treatment restriction. Patients should be assessed for response to the treatment they are ceasing at the time the application to swap therapy is being made. Patients who fail to demonstrate a response or for whom no assessment results are submitted with the application to swap therapy may not re-commence PBS-subsidised treatment with the drug they are ceasing.

Note

Applications for patients who wish to swap to an alternate PAH agent should be accompanied by the previously approved authority prescription, or remaining repeats, for the treatment the patient is ceasing.

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

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**Note**

Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 or Initial 2 (new patients) or Initial 3 (change or re-commencement of therapy for all patients) or Continuing treatment (all patients) - balance of supply

**Clinical criteria:**

Patient must have received insufficient therapy with this agent under the Initial 1 (new patients) restriction to complete a maximum of six months of treatment; OR

Patient must have received insufficient therapy with this agent under the Initial 2 (new patients) restriction to complete a maximum of six months of treatment; OR

Patient must have received insufficient therapy with this agent under the Initial 3 (change or re-commencement of therapy for all patients) restriction to complete a maximum of six months of treatment; OR

Patient must have received insufficient therapy with this agent under the Continuing treatment (all patients) restriction to complete a maximum of six months of treatment, AND

The treatment must be the sole PBS-subsidised PAH agent for this condition, AND

The treatment must provide no more than the balance of up to six months treatment available under the above restrictions.

**Note**

Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authorisation under this criterion should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Continuing treatment (all patients)

**Clinical criteria:**

Patient must have received approval for initial PBS-subsidised treatment with this agent, AND

Patient must have been assessed by a physician from a designated hospital to have achieved a response to their most recent course of treatment with this agent, AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

1. a completed authority prescription form; and
2. a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
   - RHC composite assessment; and
   - ECHO composite assessment; and
   - 6 Minute Walk Test (6MWT).

Test requirements to establish response to treatment for continuation of treatment are as follows:

The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:

1. RHC plus ECHO composite assessments plus 6MWT;
2. RHC plus ECHO composite assessments;
3. RHC composite assessment plus 6MWT;
4. ECHO composite assessment plus 6MWT;
5. RHC composite assessment only;
6. ECHO composite assessment only.
The results of the same tests as conducted at baseline should be provided with each written continuing treatment application (i.e., every 6 months), except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application.

The test results provided with the application for continuing treatment must be no more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

The assessment of the patient’s response to the first and subsequent 6 month courses of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Applications for continuing treatment with a PAH agent should be made prior to the completion of the 6 month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term ‘PAH agents’ refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Caution
This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 3 months following cessation of therapy.

Note
Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Note
Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

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Authority required
Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 (new patients)

Clinical criteria:
Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent,

AND

Patient must have been assessed by a physician at a designated hospital,

AND

Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or heritable PAH; OR

Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease,
Patient must have a mean right atrial pressure of 8 mmHg or less as measured by right heart catheterisation (RHC); OR

Patient must have right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds,

AND

Patient must have failed to respond to 6 or more weeks of appropriate vasodilator treatment unless intolerance or a contraindication to such treatment exists,

AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6 Minute Walk Test (6MWT); and

(3) a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditable pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger’s physiology) are defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiogram (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient’s baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments;

(2) RHC composite assessment plus 6MWT;

(3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

(1) ECHO composite assessment plus 6MWT;

(2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Details of prior vasodilator treatment, including the dose and duration of treatment, must be provided at the time of application. Where the patient has an adverse event to a vasodilator or where vasodilator treatment is contraindicated, details of the nature of the adverse event or contraindication according to the Therapeutic Goods Administration (TGA) approved Product Information must also be provided with the application.

Response to prior vasodilator treatment is defined as follows:

For patients with 2 or more baseline tests, response to treatment is defined as 2 or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.

A maximum of 5 repeats may be requested.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease...
PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

**Note**
Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

**Note**
Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 (new patients)

Clinical criteria:

Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent,

**AND**

Patient must have been assessed by a physician at a designated hospital,

**AND**

Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH, and a mean right atrial pressure of greater than 8 mmHg, as measured by right heart catheterisation (RHC); OR

Patien must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH, with right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds; OR

Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease and a mean right atrial pressure greater than 8 mmHg, as measured by RHC; OR

Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease with right ventricular function assessed by ECHO where a RHC cannot be performed on clinical grounds,

**AND**

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

1. a completed authority prescription form; and
2. a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
   - (i) RHC composite assessment; and
   - (ii) ECHO composite assessment; and
   - (iii) 6 Minute Walk Test (6MWT); and
3. a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditable pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger’s physiology) are defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or
(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient’s baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending
HIGHERLY SPECIALISED DRUGS PROGRAM (Public Hospital)

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(order, for the purposes of initiation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments;
(2) RHC composite assessment plus 6MWT;
(3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

(1) ECHO composite assessment plus 6MWT;
(2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats may be requested.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

Note

Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 3 (change or re-commencement of therapy for all patients)

Clinical criteria:

Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease and must wish to re-commence PBS-subsidised therapy with this agent after a break in therapy and must have demonstrated a response to their most recent course of PBS-subsidised treatment with this agent; OR

Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease and whose most recent course of PBS-subsidised treatment was with a PAH agent other than this agent, AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and
(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form; and
(3) the results of the patient’s response to treatment with their last course of PBS-subsidised PAH agent.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or
improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats may be requested.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term ‘PAH agents’ refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Swapping between PAH agents:

Patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment with 1 of these 7 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent’s restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. New baselines may be submitted where the patient has failed to respond to their current treatment.

Eligible patients may only swap between PAH agents if they have not failed prior PBS-subsidised treatment with that agent.

For eligible patients, applications to swap between the 7 PAH agents must be made under the relevant initial treatment restriction. Patients should be assessed for response to the treatment they are ceasing at the time the application to swap therapy is being made. Patients who fail to demonstrate a response or for whom no assessment results are submitted with the application to swap therapy may not re-commence PBS-subsidised treatment with the drug they are ceasing.

Note

Applications for patients who wish to swap to an alternate PAH agent should be accompanied by the previously approved authority prescription, or remaining repeats, for the treatment the patient is ceasing.

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

Note

Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 or Initial 2 (new patients) or Initial 3 (change or re-commencement of therapy for all patients) or Continuing treatment (all patients) – balance of supply

Clinical criteria:

Patient must have received insufficient therapy with this agent under the Initial 1 (new patients) restriction to complete a maximum of six months of treatment; OR

Patient must have received insufficient therapy with this agent under the Initial 2 (new patients) restriction to complete a maximum of six months of treatment; OR

Patient must have received insufficient therapy with this agent under the Initial 3 (change or re-commencement of therapy for all patients) restriction to complete a maximum of six months of treatment; OR

Patient must have received insufficient therapy with this agent under the Continuing treatment (all patients) restriction to complete a maximum of six months of treatment,

AND

The treatment must be the sole PBS-subsidised PAH agent for this condition,
**HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)**

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The treatment must provide no more than the balance of up to six months treatment available under the above restrictions.

**Note**

Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authorisation under this criterion should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Continuing treatment (all patients)

**Clinical criteria:**

Patient must have received approval for initial PBS-subsidised treatment with this agent,

AND

Patient must have been assessed by a physician from a designated hospital to have achieved a response to their most recent course of treatment with this agent,

AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

1. a completed authority prescription form; and
2. a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
   i. RHC composite assessment; and
   ii. ECHO composite assessment; and
   iii. 6 Minute Walk Test (6MWT).

Test requirements to establish response to treatment for continuation of treatment are as follows:

The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:

1. RHC plus ECHO composite assessments plus 6MWT;
2. RHC plus ECHO composite assessments;
3. RHC composite assessment plus 6MWT;
4. ECHO composite assessment plus 6MWT;
5. RHC composite assessment only;
6. ECHO composite assessment only.

The results of the same tests as conducted at baseline should be provided with each written continuing treatment application (i.e., every 6 months), except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application.

The test results provided with the application for continuing treatment must be no more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

The assessment of the patient’s response to the first and subsequent 6 month courses of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Applications for continuing treatment with a PAH agent should be made prior to the completion of the 6 month treatment course to ensure.
continuity for those patients who respond to treatment, as assessed by the treating physician.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

**Note**

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

**Note**

Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

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**TADALAFIL**

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 (new patients)

**Clinical criteria:**

Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent,

AND

Patient must have been assessed by a physician at a designated hospital,

AND

Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH; OR

Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease,

AND

Patient must have a mean right atrial pressure of 8 mmHg or less as measured by right heart catheterisation (RHC); OR

Patient must have right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds,

AND

Patient must have failed to respond to 6 or more weeks of appropriate vasodilator treatment unless intolerance or a contraindication to such treatment exists,

AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6 Minute Walk Test (6MWT); and

(3) a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditable pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger’s physiology) are defined as
follows:

(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient’s baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments;
(2) RHC composite assessment plus 6MWT;
(3) ECHO composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

(1) ECHO composite assessment plus 6MWT;
(2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Details of prior vasodilator treatment, including the dose and duration of treatment, must be provided at the time of application. Where the patient has an adverse event to a vasodilator or where vasodilator treatment is contraindicated, details of the nature of the adverse event or contraindication according to the Therapeutic Goods Administration (TGA) approved Product Information must also be provided with the application.

Response to prior vasodilator treatment is defined as follows:

For patients with 2 or more baseline tests, response to treatment is defined as 2 or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.

A maximum of 5 repeats may be requested.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

**Note**
Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

**Note**
Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

**Authority required**
Pulmonary arterial hypertension (PAH)
Clinical criteria:

Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent,

AND

Patient must have been assessed by a physician at a designated hospital,

AND

Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH, and a mean right atrial pressure of greater than 8 mmHg, as measured by right heart catheterisation (RHC); OR

Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH, with right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds; OR

Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease and a mean right atrial pressure greater than 8 mmHg, as measured by RHC; OR

Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease with right ventricular function assessed by ECHO where a RHC cannot be performed on clinical grounds,

AND

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6 Minute Walk Test (6MWT); and

(3) a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditable pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient’s baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments;

(2) RHC composite assessment plus 6MWT;

(3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

(1) ECHO composite assessment plus 6MWT;

(2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats may be requested.

The term ‘PAH agents’ refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.
**HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)**

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Applications for authority to prescribe should be forwarded to:

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Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

**Note**

Refer to the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au) for a list of designated hospitals.

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 3 (change or re-commencement of therapy for all patients)

**Clinical criteria:**

Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease and must wish to re-commence PBS-subsidised therapy with this agent after a break in therapy and must have demonstrated a response to their most recent course of PBS-subsidised treatment with this agent; OR

Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease and whose most recent course of PBS-subsidised treatment was with a PAH agent other than this agent, AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form; and

(3) the results of the patient’s response to treatment with their last course of PBS-subsidised PAH agent.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats may be requested.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term ‘PAH agents’ refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Swapping between PAH agents:

Patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment with 1 of these 7 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent’s restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. New baselines may be submitted where the patient has failed to respond to their current treatment.

Eligible patients may only swap between PAH agents if they have not failed prior PBS-subsidised treatment with that agent.

For eligible patients, applications to swap between the 7 PAH agents must be made under the relevant initial treatment restriction. Patients should
be assessed for response to the treatment they are ceasing at the time the application to swap therapy is being made. Patients who fail to demonstrate a response or for whom no assessment results are submitted with the application to swap therapy may not re-commence PBS-subsidised treatment with the drug they are ceasing.

**Note**
Applications for patients who wish to swap to an alternate PAH agent should be accompanied by the previously approved authority prescription, or remaining repeats, for the treatment the patient is ceasing.

**Note**
Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

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**Note**
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**Authority required**
Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 or Initial 2 (new patients) or Initial 3 (change or re-commencement of therapy for all patients) or Continuing treatment (all patients) – balance of supply

**Clinical criteria:**
Patient must have received insufficient therapy with this agent under the Initial 1 (new patients) restriction to complete a maximum of six months of treatment; OR
Patient must have received insufficient therapy with this agent under the Initial 2 (new patients) restriction to complete a maximum of six months of treatment; OR
Patient must have received insufficient therapy with this agent under the Initial 3 (change or re-commencement of therapy for all patients) restriction to complete a maximum of six months of treatment; OR
Patient must have received insufficient therapy with this agent under the Continuing treatment (all patients) restriction to complete a maximum of six months of treatment,

**AND**
The treatment must be the sole PBS-subsidised PAH agent for this condition,

**AND**
The treatment must provide no more than the balance of up to six months treatment available under the above restrictions.

**Note**
Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authorisation under this criterion should be forwarded to:

Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

**Authority required**
Pulmonary arterial hypertension (PAH)

Treatment Phase: Continuing treatment (all patients)

**Clinical criteria:**
Patient must have received approval for initial PBS-subsidised treatment with this agent,

**AND**
Patient must have been assessed by a physician from a designated hospital to have achieved a response to their most recent course of treatment with this agent.

**AND**
The treatment must be the sole PBS-subsidised PAH agent for this condition.
Applications for authorisation must be in writing and must include:

1. a completed authority prescription form; and
2. a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
   i. RHC composite assessment; and
   ii. ECHO composite assessment; and
   iii. 6 Minute Walk Test (6MWT).

Test requirements to establish response to treatment for continuation of treatment are as follows:
The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:

1. RHC plus ECHO composite assessments plus 6MWT;
2. RHC plus ECHO composite assessments;
3. RHC composite assessment plus 6MWT;
4. ECHO composite assessment plus 6MWT;
5. RHC composite assessment only;
6. ECHO composite assessment only.

The results of the same tests as conducted at baseline should be provided with each written continuing treatment application (i.e., every 6 months), except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application.

The test results provided with the application for continuing treatment must be no more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

The assessment of the patient’s response to the first and subsequent 6 month courses of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Applications for continuing treatment with a PAH agent should be made prior to the completion of the 6 month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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**HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)**
SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS

PITUITARY AND HYPOTHALAMIC HORMONES AND ANALOGUES

HYPOTHALAMIC HORMONES

Somatostatin and analogues

LANREOTIDE

Authority required (STREAMLINED)

4570
Acromegaly

Clinical criteria:
The condition must be active,

AND

Patient must have persistent elevation of mean growth hormone levels of greater than 2.5 micrograms per litre,

AND

The treatment must be after failure of other therapy including dopamine agonists; OR

The treatment must be as interim treatment while awaiting the effects of radiotherapy and where treatment with dopamine agonists has failed; OR

The treatment must be in a patient who is unfit for or unwilling to undergo surgery and where radiotherapy is contraindicated,

AND

The treatment must cease in a patient treated with radiotherapy if there is biochemical evidence of remission (normal IGF1) after lanreotide has been withdrawn for at least 4 weeks (8 weeks after the last dose),

AND

The treatment must cease if IGF1 is not lower after 3 months of treatment.

In a patient treated with radiotherapy, lanreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission.

Authority required (STREAMLINED)

4575
Functional carcinoid tumour

Clinical criteria:
The condition must be causing intractable symptoms,

AND

Patient must have experienced on average over 1 week, 3 or more episodes per day of diarrhoea and/or flushing, which persisted despite the use of anti-histamines, anti-serotonin agents and anti-diarrhoea agents,

AND

Patient must be one in whom surgery or antineoplastic therapy has failed or is inappropriate,

AND

The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 3 months' therapy at a dose of 120 mg every 28 days.

Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.

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LANREOTIDE

Authority required (STREAMLINED)

4567
Acromegaly

Clinical criteria:
The condition must be active,

AND

Patient must have persistent elevation of mean growth hormone levels of greater than 2.5 micrograms per litre,
Patient must have persistent elevation of mean growth hormone levels of greater than 2.5 micrograms per litre, AND

The treatment must be after failure of other therapy including dopamine agonists; OR

The treatment must be as interim treatment while awaiting the effects of radiotherapy and where treatment with dopamine agonists has failed; OR

The treatment must be in a patient who is unfit for or unwilling to undergo surgery and where radiotherapy is contraindicated, AND

The treatment must cease in a patient treated with radiotherapy if there is biochemical evidence of remission (normal IGF1) after lanreotide has been withdrawn for at least 4 weeks (6 weeks after the last dose), AND

The treatment must cease if IGF1 is not lower after 3 months of treatment. In a patient treated with radiotherapy, lanreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission.

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**OCTREOTIDE**

**Authority required (STREAMLINED)**

*4563*  
Acromegaly  
**Clinical criteria:**  
The condition must be controlled with octreotide immediate release injections, AND  
The treatment must cease in a patient treated with radiotherapy if there is biochemical evidence of remission (normal IGF1) after octreotide has been withdrawn for at least 4 weeks (8 weeks after the last dose), AND  
The treatment must cease if IGF1 is not lower after 3 months of treatment. In a patient treated with radiotherapy, octreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission

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**Authority required (STREAMLINED)**

*4561*  
Functional carcinoid tumour  
**Clinical criteria:**  
Patient must have achieved symptom control on octreotide immediate release injections, AND  
The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 3 months' therapy at a dose of 30 mg every 28 days and having allowed adequate rescue therapy with octreotide immediate release injections. Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.

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**Authority required (STREAMLINED)**

*4564*  
Vasoactive intestinal peptide secreting tumour (VIPoma)  
**Clinical criteria:**  
Patient must have achieved symptom control on octreotide immediate release injections, AND  
The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 3 months' therapy at a dose of 30 mg every 28 days and having allowed adequate rescue therapy with octreotide immediate release injections. Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.

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HIGHERLY SPECIALISED DRUGS PROGRAM (Public Hospital)

**HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)**

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<td>Functional carcinoid tumour or vasoactive intestinal peptide secreting tumour (VIPoma) causing intractable symptoms. The patient must have experienced on average over 1 week, 3 or more episodes per day of diarrhoea and/or flushing, which persisted despite the use of anti-histamines, anti-serotonin agents and anti-diarrhoea agents, and surgery or antineoplastic therapy must have failed or be inappropriate. Treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 2 months' therapy. Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose</td>
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**CALCULM HOMEOSTASIS**

**ANTI-PARATHYROID AGENTS**

*Other anti-parathyroid agents*

**CINACALCET**

**Authority required (STREAMLINED)**

3323 Management, including initiation and stabilisation, by a nephrologist, of a patient with chronic kidney disease on dialysis who has sustained secondary hyperparathyroidism with iPTH of at least 50 pmol per L, not responding to conventional therapy

**Authority required (STREAMLINED)**

3324 Management, including initiation and stabilisation, by a nephrologist, of a patient with chronic kidney disease on dialysis who has sustained secondary hyperparathyroidism with iPTH of at least 15 pmol per L and less than 50 pmol per L AND an (adjusted) serum calcium concentration at least 2.6 mmol per L, not responding to conventional treatment

**Note** During the titration phase, intact PTH should be monitored 4 weekly (measured at least 12 hours post dose) and dose titrated until an appropriate iPTH concentration is achieved. During the titration phase, approval will be limited to sufficient supply for 4 weeks treatment at a time, with doses between 30 and 180 mg per day according to the patient’s response and tolerability.

During the maintenance phase, approval will be limited to provide sufficient quantity for 4 weeks treatment up to a maximum of 6 months supply for doses between 30 and 180 mg per day according to the patient’s response and tolerability. Intact PTH should be monitored quarterly (measured at least 12 hours post dose) and dose adjusted as necessary to maintain an appropriate iPTH concentration.

"Sustained" means the abnormality was detected on at least 2 blood samples collected over a period of 2 to 4 months.

**Note** Special Pricing Arrangements apply.

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887
## ANTIIINFECTIVES FOR SYSTEMIC USE

### ANTIBACTERIALS FOR SYSTEMIC USE

#### MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS

**Macrolides**

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<td>5616N</td>
<td>Azithromycin 600 mg tablet, 8</td>
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<td>Prophylaxis against Mycobacterium avium complex infections in HIV-positive patients with CD4 cell counts of less than 75 per cubic millimetre</td>
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<td>Zithromax PF</td>
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<td>5625C</td>
<td>Clarithromycin 250 mg tablet, 100</td>
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<td>Klacid AB</td>
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<td>5624B</td>
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<td>Treatment of Mycobacterium avium complex infections</td>
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### ANTIMYCOBACTERIALS

#### DRUGS FOR TREATMENT OF TUBERCULOSIS

**Antibiotics**

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<td>9541E</td>
<td>Rifabutin 150 mg capsule, 30</td>
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<td>Prophylaxis against Mycobacterium avium complex infections in HIV-positive patients with CD4 cell counts of less than 75 per cubic millimetre</td>
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### ANTIVIRALS FOR SYSTEMIC USE

#### DIRECT ACTING ANTIVIRALS

**Nucleosides and nucleotides excl. reverse transcriptase inhibitors**

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<td>5620T</td>
<td>Cidofovir 375 mg/5 mL injection, 1 x 5 mL vial</td>
<td>Authority required (STREAMLINED)</td>
<td>Treatment of cytomegalovirus retinitis in patients with AIDS</td>
<td>4 3 ..</td>
<td>*3600.00</td>
<td>Vistide GI</td>
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<tr>
<td>5749N</td>
<td>Ganciclovir 500 mg injection, 5 x 500 mg vials</td>
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<td>Prophylaxis of cytomegalovirus disease in solid organ transplant patients at risk of cytomegalovirus disease</td>
<td>2 1 ..</td>
<td>*560.00</td>
<td>Cymevene RO</td>
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*Note: The document is a list of highly specialised drugs, including codes, names, restrictions, manner of administration, forms, maximum quantities, number of reports, premiums, dispensed prices, and brand names and manufacturers.*
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<td>Prophylaxis of cytomegalovirus (CMV) infection and disease following renal transplantation in patients at risk of CMV disease</td>
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<td>valaciclovir 500 mg tablet, 100</td>
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<td>3420</td>
<td>Cytomegalovirus retinitis in patients with acquired immunodeficiency syndrome</td>
<td>9569P</td>
<td>valganciclovir 450 mg tablet, 60</td>
<td>2 5 ..</td>
<td>4491.60 Valcyte RO</td>
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<td>3421</td>
<td>Prophylaxis of cytomegalovirus infection and disease in solid organ transplant patients at risk of cytomegalovirus disease</td>
<td>9655E</td>
<td>valganciclovir 50 mg/mL oral liquid: powder for, 100 mL</td>
<td>11 5 ..</td>
<td>4574.79 Valcyte RO</td>
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<td></td>
<td>Phosphonic acid derivatives</td>
<td>3322</td>
<td>FOSCARNET</td>
<td>Authority required (STREAMLINED)</td>
<td>Treatment of cytomegalovirus retinitis in patients with AIDS</td>
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<td>3378</td>
<td>Authority required (STREAMLINED)</td>
<td>Treatment of aciclovir-resistant herpes simplex virus infection in immunocompromised patients with HIV infection</td>
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<td>5747L</td>
<td>FOSCARNET SODIUM I.V. infusion 24 mg per mL, 250 mL bottle, 6</td>
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**HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)**

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<td>4182</td>
<td>Chronic genotype 1 hepatitis C infection</td>
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</table>

**Clinical criteria:**

Patient must have compensated liver disease,

**AND**

Patient must have received no more than one prior treatment with interferon alfa or peginterferon alfa for hepatitis C,

**AND**

The treatment must be in combination with peginterferon alfa and ribavirin,

**AND**

The treatment must be limited to a maximum duration of 32 weeks in patients without hepatic cirrhosis who were partial responders or relapers to the prior course of interferon based therapy for hepatitis C; OR

The treatment must be limited to a maximum duration of 44 weeks in patients without hepatic cirrhosis who were null responders to the prior course of interferon based therapy for hepatitis C; OR

The treatment must be limited to a maximum duration of 44 weeks for all patients with hepatic cirrhosis,

**AND**

The treatment must cease after the first 8 weeks of boceprevir treatment if plasma HCV RNA is detectable by an HCV RNA qualitative assay at treatment week 12,

**AND**

The treatment must cease after the first 20 weeks of boceprevir treatment if plasma HCV RNA is detectable by an HCV RNA qualitative assay at treatment week 24.

**Population criteria:**

Patient must be 18 years or older,

**AND**

Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

**Treatment criteria:**

Must be treated in an accredited treatment centre.

Chronic genotype 1 hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient’s medical records.

Patients who have received prior treatment with an NS3/4A protease inhibitor are not eligible to receive PBS-subsidised boceprevir, except where the patient has developed an intolerance to the other NS3/4A protease inhibitor of a severity necessitating permanent treatment withdrawal.

Details of the intolerance must be documented in the patient’s medical records.

For patients without hepatic cirrhosis who were partial responders or relapers to the prior course of interferon based therapy, a maximum of 7 repeats may be prescribed.

For patients without hepatic cirrhosis who were null responders to the prior course of interferon based therapy, a maximum of 10 repeats may be prescribed.

For patients with hepatic cirrhosis, a maximum of 10 repeats may be prescribed.

**Authority required (STREAMLINED)**

| 4202 | Chronic genotype 1 hepatitis C infection            |                  |             |           |                              |                            |

**Clinical criteria:**

Patient must have compensated liver disease,

**AND**

Patient must not have received prior interferon alfa or peginterferon alfa treatment for hepatitis C,

**AND**

The treatment must be in combination with peginterferon alfa and ribavirin,

**AND**

The treatment must be limited to a maximum duration of 24 weeks in patients without hepatic cirrhosis; OR

The treatment must be limited to a maximum duration of 44 weeks in patients with hepatic cirrhosis,

**AND**

The treatment must cease after the first 20 weeks of boceprevir treatment if plasma HCV RNA is detectable by an HCV RNA qualitative assay at treatment week 24.

**Population criteria:**

Patient must be 18 years or older,
Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

**Treatment criteria:**

Must be treated in an accredited treatment centre.

Evidence of chronic genotype 1 hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient’s medical records.

Patients who have received prior treatment with an NS3/4A protease inhibitor are not eligible to receive PBS-subsidised boceprevir, except where the patient has developed an intolerance to the other NS3/4A protease inhibitor of a severity necessitating permanent treatment withdrawal. Details of the intolerance must be documented in the patient’s medical records.

For patients without hepatic cirrhosis, a maximum of 5 repeats may be prescribed.

For patients with hepatic cirrhosis, a maximum of 10 repeats may be prescribed.

**Note**

No increase in the maximum quantity or number of units may be authorised.

**Note**

Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:

(a) a nurse educator/counsellor for patients; and

(b) 24-hour access by patients to medical advice; and

(c) an established liver clinic.

---

**DARUNAVIR**

**Authority required (STREAMLINED)**

**3595**

Treatment of HIV infection, in addition to optimised background therapy in combination with other antiretroviral agents, and co-administered with 100 mg ritonavir twice daily in an antiretroviral experienced patient who, after at least one antiretroviral regimen, has experienced virological failure or clinical failure or genotypic resistance.

Virological failure is defined as a viral load greater than 400 copies per mL on two consecutive occasions, while clinical failure is linked to emerging signs and symptoms of progressing HIV infection or treatment-limiting toxicity.

**DARUNAVIR**

**Authority required (STREAMLINED)**

**4313**

Human immunodeficiency virus (HIV) infection

**Clinical criteria:**

The treatment must be in addition to optimised background therapy,

AND

The treatment must be in combination with other antiretroviral agents,

AND

The treatment must be co-administered with 100 mg ritonavir,

AND

Patient must have experienced virological failure or clinical failure or genotypic resistance after at least one antiretroviral regimen,

AND

Patient must not have demonstrated darunavir resistance associated mutations detected on resistance testing.

Virological failure is defined as a viral load greater than 400 copies per mL on two consecutive occasions, while clinical failure is linked to emerging signs and symptoms of progressing HIV infection or treatment-limiting toxicity.

**FOSAMPRENAVIR**

**Authority required (STREAMLINED)**

**4512**

HIV infection
**HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)**

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**INDINAVIR**

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**RITONAVIR**

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<td></td>
<td>The treatment must be limited to a maximum duration of 12 weeks,</td>
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<td></td>
<td>The treatment must cease if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is greater than 1000 IU/mL.</td>
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<td><strong>Population criteria:</strong></td>
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<tr>
<td></td>
<td>Patient must be 18 years or older,</td>
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<td>AND</td>
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<tr>
<td></td>
<td>Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.</td>
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<td></td>
<td><strong>Treatment criteria:</strong></td>
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<tr>
<td></td>
<td>Must be treated in an accredited treatment centre.</td>
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<tr>
<td></td>
<td>Evidence of chronic genotype 1 hepatitis C infection (repeatedly anti-HCV positive and HCV RNA positive) must be documented in the patient’s medical records.</td>
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<td></td>
<td>Patients who have received prior treatment with an NS3/4A protease inhibitor are not eligible to receive PBS-subsidised telaprevir, except where the patient has developed an intolerance to the other NS3/4A protease inhibitor of a severity necessitating permanent treatment withdrawal. Details of the intolerance must be documented in the patient’s medical records.</td>
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<td></td>
<td><strong>Authority required (STREAMLINED)</strong></td>
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<td>4191</td>
<td>Chronic genotype 1 hepatitis C infection</td>
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<td><strong>Clinical criteria:</strong></td>
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<tr>
<td></td>
<td>Patient must have compensated liver disease,</td>
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<td></td>
<td>AND</td>
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</tr>
</tbody>
</table>
### Patient must have received prior treatment with interferon alfa or peginterferon alfa for hepatitis C,

**AND**

The treatment must be in combination with peginterferon alfa and ribavirin.

**AND**

The treatment must be limited to a maximum duration of 12 weeks.

**AND**

The treatment must cease if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is greater than 1000 IU/mL.

**Population criteria:**

Patient must be 18 years or older,

**AND**

Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

**Treatment criteria:**

Must be treated in an accredited treatment centre.

Evidence of chronic genotype 1 hepatitis C infection (repeatedly anti-HCV positive and HCV RNA positive) must be documented in the patient’s medical records.

Patients who have received prior treatment with an NS3/4A protease inhibitor are not eligible to receive PBS-subsidised telaprevir, except where the patient has developed an intolerance to the other NS3/4A protease inhibitor of a severity necessitating permanent treatment withdrawal. Details of the intolerance must be documented in the patient’s medical records.

**Note**

No increase in the maximum quantity or number of units may be authorised.

**Note**

No increase in the maximum number of repeats may be authorised.

**Note**

Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:

(a) a nurse educator/counsellor for patients; and

(b) 24-hour access by patients to medical advice; and

(c) an established liver clinic.

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>Dispensed Price for Max. Qty $</th>
<th>Brand Name and Manufacturer</th>
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<td>2437G</td>
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<td>..</td>
<td>*14865.72</td>
<td>Incivo JC</td>
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</tbody>
</table>

### TIPRANAVIR

**Authority required (STREAMLINED)**

**3601**

Treatment of HIV infection, in addition to optimised background therapy in combination with other antiretroviral agents, and co-administered with 200 mg ritonavir twice daily in an antiretroviral experienced patient who, after each of at least three different antiretroviral regimens that have included one drug from at least 3 different antiretroviral classes, has experienced virological failure or clinical failure or genotypic resistance.

Virological failure is defined as a viral load greater than 400 copies per mL on two consecutive occasions, while clinical failure is linked to emerging signs and symptoms of progressing HIV infection or treatment-limiting toxicity.

**Note**

Special Pricing Arrangements apply.

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
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<th>Brand Name and Manufacturer</th>
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<td>*2142.00</td>
<td>Aptivus BY</td>
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</table>

### Nucleoside and nucleotide reverse transcriptase inhibitors

#### ABACAVIR

**Authority required (STREAMLINED)**

**4512**

HIV infection

Treatment Phase: Initial

Clinical criteria:

Patient must be antiretroviral treatment naïve,

**AND**

The treatment must be in combination with other antiretroviral agents.
<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
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<td>HIV infection</td>
<td>Treatment Phase: Continuing</td>
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<tr>
<td></td>
<td>The treatment must be in combination with other antiretroviral agents.</td>
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<td>5602W</td>
<td>abacavir 20 mg/mL oral liquid, 240 mL</td>
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<td>abacavir 300 mg tablet, 60</td>
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<td>5</td>
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<td>*564.00</td>
<td>Ziagen</td>
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<td>ADEFOVIR DIPIVOXIL Authority required (STREAMLINED)</td>
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<tr>
<td>3973</td>
<td>Chronic hepatitis B in a patient without cirrhosis who has failed antiretroviral therapy and who satisfies all of the following criteria:</td>
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<td>(a) Repeatedly elevated serum ALT levels while on concurrent antiretroviral therapy of greater than or equal to 6 months duration in conjunction with documented chronic hepatitis B infection; or</td>
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<td>(b) Repeatedly elevated HBV DNA levels one log greater than the nadir value or failure to achieve a 1 log reduction in HBV DNA within 3 months, whilst on previous antiretroviral therapy except in patients with evidence of poor compliance</td>
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<tr>
<td>3974</td>
<td>Chronic hepatitis B in a patient with cirrhosis who has failed antiretroviral therapy and who has detectable HBV DNA.</td>
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<td></td>
<td>Persons with Child’s class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy</td>
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<td></td>
<td><strong>Note</strong></td>
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<td></td>
<td>Patients may receive treatment in combination with lamivudine but not with other PBS-subsidised antiretroviral therapy.</td>
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<td>5606C</td>
<td>adeovir dipivoxil 10 mg tablet, 30</td>
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<td>5</td>
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<td>*1250.00</td>
<td>Hepsera</td>
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<td>DIDANOSINE Authority required (STREAMLINED)</td>
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<tr>
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<td></td>
<td>Treatment Phase: Initial</td>
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<td></td>
<td><strong>Clinical criteria:</strong></td>
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<tr>
<td></td>
<td>The treatment must be in combination with other antiretroviral agents.</td>
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<tr>
<td>4454</td>
<td>HIV infection</td>
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<tr>
<td></td>
<td>Treatment Phase: Continuing</td>
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<td></td>
<td><strong>Clinical criteria:</strong></td>
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<td></td>
<td>The treatment must be in combination with other antiretroviral agents.</td>
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<td>5663C</td>
<td>didanosine 125 mg capsule: enteric, 30</td>
<td>2</td>
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<td>*280.86</td>
<td>Videx EC</td>
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<td>5664D</td>
<td>didanosine 200 mg capsule: enteric, 30</td>
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<td>5</td>
<td>..</td>
<td>*326.80</td>
<td>Videx EC</td>
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<td>5665E</td>
<td>didanosine 250 mg capsule: enteric, 30</td>
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<td>*408.48</td>
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<td>5666F</td>
<td>didanosine 400 mg capsule: enteric, 30</td>
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<td>4512</td>
<td>HIV infection</td>
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</tbody>
</table>
## Treatment Phase: Initial

**Clinical criteria:**

- Patient must be antiretroviral treatment naive,
- AND
- The treatment must be in combination with other antiretroviral agents.

**Authority required (STREAMLINED)**

**4454**

- HIV infection

**Dispensed Price for Max. Qty $**

<table>
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<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
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<td>5709L</td>
<td>entecitabine 200 mg capsule, 30</td>
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<td>*564.00</td>
<td>Emtriva GI</td>
</tr>
</tbody>
</table>

### ENTECAVIR

**Authority required (STREAMLINED)**

**3964**

- Chronic hepatitis B in a patient without cirrhosis who has failed lamivudine and who satisfies all of the following criteria:
  - Repeatedly elevated serum ALT levels while on concurrent antihepadnaviral therapy of greater than or equal to 6 months duration in conjunction with documented chronic hepatitis B infection; or
  - Repeatedly elevated HBV DNA levels one log greater than the nadir value or failure to achieve a 1 log reduction in HBV DNA within 3 months, whilst on previous antihepadnaviral therapy except in patients with evidence of poor compliance

**Authority required (STREAMLINED)**

**3966**

- Chronic hepatitis B in a patient with cirrhosis who has detectable HBV DNA.
- Persons with Child’s class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy

**Note**

- PBS-subsidised entecavir monohydrate must be used as monotherapy.

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<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
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<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>5712P</td>
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<td>5</td>
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<td>*1250.00</td>
<td>Baraclude BQ</td>
</tr>
</tbody>
</table>

### ENTECAVIR

**Authority required (STREAMLINED)**

**3961**

- Chronic hepatitis B in a patient without cirrhosis who satisfies all of the following criteria:
  - Elevated HBV DNA levels - greater than 20,000 IU/mL (100,000 copies/mL) if HBeAg positive, or greater than 2,000 IU/mL (10,000 copies/mL) if HBeAg negative - in conjunction with documented chronic hepatitis B infection;
  - Evidence of chronic liver injury as determined by:
    - Confirmed elevated serum ALT;
    - Liver biopsy

**Authority required (STREAMLINED)**

**3962**

- Chronic hepatitis B in a patient with cirrhosis who has detectable HBV DNA.
- Persons with Child’s class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy

**Note**

- PBS-subsidised entecavir monohydrate must be used as monotherapy.

<table>
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<tr>
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</table>

### LAMIVUDINE

**Authority required (STREAMLINED)**

**4512**

- HIV infection

**Dispensed Price for Max. Qty $**

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<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
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</tbody>
</table>
Clinical criteria:
Patient must be antiretroviral treatment naive, AND
The treatment must be in combination with other antiretroviral agents.

**Authority required (STREAMLINED)**

4454
HIV infection
Treatment Phase: Continuing

Clinical criteria:
Patient must have previously received PBS-subsidised therapy for HIV infection, AND
The treatment must be in combination with other antiretroviral agents.

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
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<th>Brand Name and Manufacturer</th>
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<tr>
<td>5773W</td>
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</table>

LAMIVUDINE

**Authority required (STREAMLINED)**

3961
Chronic hepatitis B in a patient without cirrhosis who satisfies all of the following criteria:

(1) Elevated HBV DNA levels - greater than 20,000 IU/mL (100,000 copies/mL) if HBeAg positive, or greater than 2,000 IU/mL (10,000 copies/mL) if HBeAg negative - in conjunction with documented chronic hepatitis B infection;

(2) Evidence of chronic liver injury as determined by:

(a) Confirmed elevated serum ALT; or

(b) Liver biopsy

**Authority required (STREAMLINED)**

3962
Chronic hepatitis B in a patient with cirrhosis who has detectable HBV DNA.

Persons with Child’s class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy

<table>
<thead>
<tr>
<th>Code</th>
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<td>5771R</td>
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<td>*294.50</td>
<td>Zeffix AS</td>
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</table>

STAVUDINE

**Authority required (STREAMLINED)**

4512
HIV infection
Treatment Phase: Initial

Clinical criteria:
Patient must be antiretroviral treatment naive, AND
The treatment must be in combination with other antiretroviral agents.

**Authority required (STREAMLINED)**

4454
HIV infection
Treatment Phase: Continuing

Clinical criteria:
### HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

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<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
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<th>No. of Rpts</th>
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<td>*889.80</td>
<td>Zerit BQ</td>
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</tbody>
</table>

**TELBIVUDINE**

**Authority required (STREAMLINED)**

3969

Treatment, as sole PBS-subsidised therapy, in a patient with chronic hepatitis B without cirrhosis who is nucleoside analogue naive and satisfies all of the following criteria:

1. Elevated HBV DNA levels - greater than 20,000 IU/mL (100,000 copies/mL) if HBeAg positive, or greater than 2,000 IU/mL (10,000 copies/mL) if HBeAg negative - in conjunction with documented hepatitis B infection;

2. Evidence of chronic liver injury as determined by:
   
   (a) Confirmed elevated serum ALT; or
   
   (b) Liver biopsy

**Authority required (STREAMLINED)**

3970

Treatment, as sole PBS-subsidised therapy, in a patient with chronic hepatitis B with cirrhosis who is nucleoside analogue naive and who has detectable HBV DNA.

Persons with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy

9562G  telbivudine 600 mg tablet, 28                         | 2               | 5          | ..        | *501.76                      | Sebivo NV                   |

**TENOFOVIR**

**Authority required (STREAMLINED)**

4512  HIV infection

Treatment Phase: Initial

**Clinical criteria:**

Patient must be antiretroviral treatment naive,

AND

The treatment must be in combination with other antiretroviral agents.

**Authority required (STREAMLINED)**

4454  HIV infection

Treatment Phase: Continuing

**Clinical criteria:**

Patient must have previously received PBS-subsidised therapy for HIV infection,

AND

The treatment must be in combination with other antiretroviral agents.

**Authority required (STREAMLINED)**

4489  Chronic hepatitis B

**Clinical criteria:**

Patient must not have cirrhosis,

AND

Patient must be nucleoside analogue naive,

AND

Patient must have elevated HBV DNA levels greater than 20,000 IU/mL (100,000 copies/mL) if HBeAg positive, in conjunction with documented hepatitis B infection; OR

Patient must have elevated HBV DNA levels greater than 2,000 IU/mL (10,000 copies/mL) if HBeAg negative, in conjunction with documented hepatitis B infection; OR

Patient must have elevated HBV DNA levels greater than 20,000 IU/mL (100,000 copies/mL) if HBeAg positive, in conjunction with documented hepatitis B infection; OR

Patient must have elevated HBV DNA levels greater than 2,000 IU/mL (10,000 copies/mL) if HBeAg negative, in conjunction with documented hepatitis B infection; OR
hepatitis B infection,

AND

Patient must have evidence of chronic liver injury determined by: (i) confirmed elevated serum ALT; or (ii) liver biopsy,

AND

The treatment must be the sole PBS-subsidised therapy for this condition.

Note
Patients may receive treatment in combination with lamivudine but not with other PBS-subsidised antihepadnaviral therapy.

Authority required (STREAMLINED)

4476
Chronic hepatitis B
Clinical criteria:
Patient must have cirrhosis,

AND

Patient must be nucleoside analogue naive,

AND

Patient must have detectable HBV DNA,

AND

The treatment must be the sole PBS-subsidised therapy for this condition.

Persons with Child’s class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy.

Note
Patients may receive treatment in combination with lamivudine but not with other PBS-subsidised antihepadnaviral therapy.

Authority required (STREAMLINED)

4490
Chronic hepatitis B
Clinical criteria:
Patient must not have cirrhosis,

AND

Patient must have failed antihepadnaviral therapy,

AND

Patient must have repeatedly elevated serum ALT levels while on concurrent antihepadnaviral therapy of greater than or equal to 6 months duration, in conjunction with documented chronic hepatitis B infection; OR

Patient must have repeatedly elevated HBV DNA levels one log greater than the nadir value or failure to achieve a 1 log reduction in HBV DNA within 3 months whilst on previous antihepadnaviral therapy, except in patients with evidence of poor compliance.

Note
Patients may receive treatment in combination with lamivudine but not with other PBS-subsidised antihepadnaviral therapy.

Authority required (STREAMLINED)

4510
Chronic hepatitis B
Clinical criteria:
Patient must have cirrhosis,

AND

Patient must have failed antihepadnaviral therapy,

AND

Patient must have detectable HBV DNA.

Persons with Child’s class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy.

Note
Patients may receive treatment in combination with lamivudine but not with other PBS-subsidised antihepadnaviral therapy.

9563H
tenofovir disoproxil fumarate 300 mg tablet, 30

Max. Qty (Packs) 5
No. of Rpts
Premium $ 966.20
Dispensed Qty
Price for Max. Qty
Brand Name and Manufacturer
Viread Gilead

ZIDOVUDINE
Authority required (STREAMLINED)

4512
# HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

## HIV infection

### Treatment Phase: Initial

**Clinical criteria:**
- Patient must be antiretroviral treatment naive,
- The treatment must be in combination with other antiretroviral agents.

**Authority required (STREAMLINED)**

### 4454 HIV infection

#### Treatment Phase: Continuing

**Clinical criteria:**
- Patient must have previously received PBS-subsidised therapy for HIV infection,
- The treatment must be in combination with other antiretroviral agents.

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### Non-nucleoside reverse transcriptase inhibitors

#### Efavirenz

**Authority required (STREAMLINED)**

### 4512 HIV infection

#### Treatment Phase: Initial

**Clinical criteria:**
- Patient must be antiretroviral treatment naive,
- The treatment must be in combination with other antiretroviral agents.

### 4454 HIV infection

#### Treatment Phase: Continuing

**Clinical criteria:**
- Patient must have previously received PBS-subsidised therapy for HIV infection,
- The treatment must be in combination with other antiretroviral agents.

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#### Etravirine

**Authority required (STREAMLINED)**

### 3597 HIV infection

#### Treatment of HIV infection, in addition to optimised background therapy in combination with other antiretroviral agents in an antiretroviral experienced patient who, after each of at least three different antiretroviral regimens that have included one drug from at least 3 different antiretroviral classes, has experienced virological failure or clinical failure or genotypic resistance.

Virological failure is defined as a viral load greater than 400 copies per mL on two consecutive occasions, while clinical failure is linked to emerging signs and symptoms of progressing HIV infection or treatment-limiting toxicity.

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<td>Patient must be aged 12 years or older, AND</td>
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<td>Patient must weigh 40 kg or more.</td>
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<td>Clinical criteria:</td>
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<tr>
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<td>Patient must have previously received PBS-subsidised therapy for HIV infection.</td>
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<tr>
<td></td>
<td>Patient must be aged 12 years or older, AND</td>
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<td>Patient must weigh 40 kg or more.</td>
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<tr>
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<td>HIV infection Treatment Phase: Initial Clinical criteria: Patient must be antiretroviral treatment naive. <strong>Authority required [STREAMLINED]</strong></td>
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<tr>
<td>1491L</td>
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<td>5</td>
<td>..</td>
<td></td>
<td>*2073.36</td>
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<td><strong>LAMIVUDINE + ZIDOVUDINE</strong> Authority required [STREAMLINED]</td>
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<tr>
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<td>HIV infection Treatment Phase: Initial Clinical criteria: Patient must be antiretroviral treatment naive, AND The treatment must be in combination with other antiretroviral agents. <strong>Authority required [STREAMLINED]</strong></td>
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<td>HIV infection Treatment Phase: Continuing Clinical criteria: Patient must have previously received PBS-subsidised therapy for HIV infection, AND The treatment must be in combination with other antiretroviral agents. <strong>Authority required [STREAMLINED]</strong></td>
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<td>*968.34</td>
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<td>a Lamivudine 150 mg + Zidovudine 300 mg Alphapharm AF</td>
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<td>HIV infection Treatment Phase: Initial Clinical criteria: Patient must be antiretroviral treatment naive, AND The treatment must be in combination with other antiretroviral agents. <strong>Authority required [STREAMLINED]</strong></td>
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<td>4454</td>
<td>HIV infection</td>
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Highly Specialised Drugs Program (Public Hospital)

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<td>Clinical criteria:</td>
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<tr>
<td></td>
<td>Patient must have previously received PBS-subsidised therapy for HIV infection, AND</td>
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<td>5790R</td>
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<td>5789Q</td>
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<td>1290.00 Kaletra VE</td>
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</table>

**Tenofovir + Emtricitabine**

Authority required (STREAMLINED)

4512

HIV infection

Treatment Phase: Initial

Clinical criteria:
Patient must be antiretroviral treatment naive, AND
The treatment must be in combination with other antiretroviral agents.

4454

HIV infection

Treatment Phase: Continuing

Clinical criteria:
Patient must have previously received PBS-subsidised therapy for HIV infection, AND
The treatment must be in combination with other antiretroviral agents.

9564J

tenofovir disoproxil fumarate 300 mg + emtricitabine 200 mg tablet, 30

2 5 .. 1530.20 Truvada GI

**Tenofovir + Emtricitabine + Efavirenz**

Authority required (STREAMLINED)

4522

HIV infection

Treatment Phase: Initial

Clinical criteria:
Patient must be antiretroviral treatment naive.

4470

HIV infection

Treatment Phase: Continuing

Clinical criteria:
Patient must have previously received PBS-subsidised therapy for HIV infection.

9565K

tenofovir disoproxil fumarate 300 mg + emtricitabine 200 mg + efavirenz 600 mg tablet, 30

2 5 .. 2073.36 Atripla GI

**Tenofovir + Emtricitabine + Elvitegravir + Cobicistat**

Authority required (STREAMLINED)

4522

HIV infection

Treatment Phase: Initial

Clinical criteria:
Patient must be antiretroviral treatment naive.

4470

HIV infection

Treatment Phase: Continuing

Clinical criteria:
Patient must have previously received PBS-subsidised therapy for HIV infection.
### HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

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<td>10088Y</td>
<td>tenofovir disoproxil fumarate 300 mg + emtricitabine 200 mg + elvitegravir 150 mg + cobicistat 150 mg tablet, 30 packs</td>
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<td>5</td>
<td>..</td>
<td>*2073.36</td>
<td>Striibl GI</td>
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**Other antivirals**

**DOLUTEGRAVIR**  
**Authority required (STREAMLINED)**

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<td>HIV infection</td>
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<tr>
<td>10065R</td>
<td>dolutegravir 50 mg tablet, 30 packs</td>
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<td>5</td>
<td>..</td>
<td>*1331.10</td>
<td>Tivicay VI</td>
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**ENFUVIRIDE**  
**Authority required (STREAMLINED)**

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<td>3597</td>
<td>Treatment of HIV infection, in addition to optimised background therapy in combination with other antiretroviral agents in an antiretroviral experienced patient who, after each of at least three different antiretroviral regimens that have included one drug from at least 3 different antiretroviral classes, has experienced virological failure or clinical failure or genotypic resistance. Virological failure is defined as a viral load greater than 400 copies per mL on two consecutive occasions, while clinical failure is linked to emerging signs and symptoms of progressing HIV infection or treatment-limiting toxicity</td>
<td>2</td>
<td>5</td>
<td>..</td>
<td>*4426.00</td>
<td>Fuzeon RO</td>
</tr>
<tr>
<td>5710M</td>
<td>enfuvirtide 90 mg injection [60 x 90 mg vials] [&amp;] inert substance diluent [60 x 1.1 mL vials], 1 pack</td>
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**MARAVIROC**  
**Authority required (STREAMLINED)**

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<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>3599</td>
<td>Treatment, in addition to optimised background therapy in combination with other antiretroviral agents, of an antiretroviral experienced patient infected with only CCR5-tropic HIV-1, who, after each of at least three different antiretroviral regimens that have included one drug from at least 3 different antiretroviral classes, has experienced virological failure or clinical failure or genotypic resistance. A tropism assay to determine CCR5 only strain status is required prior to initiation. Individuals with CKCR4 tropism demonstrated at any time point are not eligible. Virological failure is defined as a viral load greater than 400 copies per mL on two consecutive occasions, while clinical failure is linked to emerging signs and symptoms of progressing HIV infection or treatment-limiting toxicity</td>
<td>2</td>
<td>5</td>
<td>..</td>
<td>*1835.40</td>
<td>Celsentri VI</td>
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<tr>
<td>5792W</td>
<td>maraviroc 150 mg tablet, 60 pack</td>
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<td>5793X</td>
<td>maraviroc 300 mg tablet, 60 pack</td>
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**RALTEGRAVIR**  
**Authority required (STREAMLINED)**

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### HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

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#### Raltegravir

**Authority required (STREAMLINED)**

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<td>*1331.10</td>
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</table>

The treatment must be in combination with other antiretroviral agents,

**AND**

Patient must be antiretroviral experienced with at least 6 months therapy with 2 alternate classes of anti-retroviral therapy,

**AND**

Patient must have a CD4 count of less than 500 per cubic millimetre; OR

Patient must have symptomatic HIV disease.

**Population criteria:**

Patient must be antiretroviral experienced with at least 6 months therapy with 2 alternate classes of anti-retroviral therapy,

**Population criteria:**

Patient must have a CD4 count of less than 500 per cubic millimetre; OR

Patient must have symptomatic HIV disease.

**Population criteria:**

Patient must have previously received PBS-subsidised therapy for HIV infection.

**Population criteria:**

Patient must be antiretroviral experienced with at least 6 months therapy with 2 alternate classes of anti-retroviral therapy,

**Population criteria:**

Patient must be antiretroviral treatment naive,

**Population criteria:**

Patient must have previously received PBS-subsidised therapy for HIV infection.

**Population criteria:**

Patient must be antiretroviral treatment naive,
### ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

#### ANTINEOPLASTIC AGENTS

**ANTIMETABOLITES**  
*Pyrimidine analogues*

**AZACITIDINE**  
*Authority required*

Initial PBS-subsidised treatment of a patient with:

1. Myelodysplastic syndrome classified as Intermediate-2 or high risk according to the International Prognostic Scoring System (IPSS); OR
2. Chronic Myelomonocytic Leukaemia (10% to 29% marrow blasts without Myeloproliferative Disorder); OR
3. Acute Myeloid Leukaemia with 20 to 30% marrow blasts and multi-lineage dysplasia, according to World Health Organisation (WHO) Classification.

Classification of a patient as Intermediate-2 requires a score of 1.5 to 2.0 on the IPSS, achieved with the possible combinations:

1. 11% to 30% marrow blasts with good karyotypic status (normal, -Y alone, del(5q) alone, del(20q) alone), and 0 to 1 cytopenias; OR
2. 11% to 20% marrow blasts with intermediate karyotypic status (other abnormalities), and 0 to 1 cytopenias; OR
3. 11% to 20% marrow blasts with good karyotypic status (normal, -Y alone, del(5q) alone, del(20q) alone), and 2 to 3 cytopenias; OR
4. 5% to 10% marrow blasts with poor karyotypic status (3 or more abnormalities or chromosome 7 anomalies), regardless of cytopenias; OR
5. 5% to 10% marrow blasts with intermediate karyotypic status (other abnormalities), and 2 to 3 cytopenias; OR
6. less than 5% marrow blasts with poor karyotypic status (3 or more abnormalities or chromosome 7 anomalies), and 2 to 3 cytopenias.

Classification of a patient as high risk requires a score of 2.5 or more on the IPSS, achieved with the possible combinations:

1. 21% to 30% marrow blasts with good karyotypic status (normal, -Y alone, del(5q) alone, del(20q) alone), and 2 to 3 cytopenias; OR
2. 21% to 30% marrow blasts with intermediate (other abnormalities) or poor karyotypic status (3 or more abnormalities or chromosome 7 anomalies), regardless of cytopenias; OR
3. 11% to 20% marrow blasts with poor karyotypic status (3 or more abnormalities or chromosome 7 anomalies), regardless of cytopenias; OR
4. 11% to 20% marrow blasts with intermediate karyotypic status (other abnormalities), and 2 to 3 cytopenias.

The first authority application must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Azacitidine PBS Authority Application - Supporting Information Form; and
- (c) a copy of the bone marrow biopsy report demonstrating that the patient has myelodysplastic syndrome, chronic myelomonocytic leukaemia or acute myeloid leukaemia; and
- (d) a copy of the full blood examination report; and
- (e) for myelodysplastic syndrome, a copy of the pathology report detailing the cytogenetics demonstrating intermediate-2 or high risk disease according to the International Prognostic Scoring System (IPSS); and
- (f) a signed patient acknowledgment form.

No more than three cycles will be authorised.

**Note**  
Any queries concerning the arrangements to prescribe azacitidine may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe azacitidine should be forwarded to:

Medicare Australia  
Prior Written Approval of Specialised Drugs  
Reply Paid 9826  
GPO Box 9826  
HOBART TAS 7001

**Note**  
Special Pricing Arrangements apply.

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<td>azacitidine 100 mg injection, 1 x 100 mg vial</td>
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<td>7700.00 Vidaza</td>
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**AZACITIDINE**  
*Authority required*

Continuing treatment of a patient with:
<table>
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<tr>
<td>9598E</td>
<td>azacitidine 100 mg injection, 1 x 100 mg vial</td>
<td>14</td>
<td>5</td>
<td>..</td>
<td>*7700.00</td>
<td>Vidaza CJ</td>
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**Note**

Special Pricing Arrangements apply.

**CYTOTOXIC ANTIBIOTICS AND RELATED SUBSTANCES**

**Anthracyclines and related substances**

**DOXORUBICIN HYDROCHLORIDE-PEGYLATED LIPOSOMAL**

**Authority required (STREAMLINED)**

<table>
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<tr>
<th>Authority required</th>
<th>Treatment of AIDS-related Kaposi's sarcoma in patients with CD4 cell counts of less than 200 per cubic millimetre and extensive mucocutaneous involvement</th>
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**Authority required (STREAMLINED)**

<table>
<thead>
<tr>
<th>Authority required</th>
<th>Treatment of AIDS-related Kaposi's sarcoma in patients with CD4 cell counts of less than 200 per cubic millimetre and extensive visceral involvement</th>
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**5705G**

doxorubicin hydrochloride-pegylated liposomal 20 mg/10 mL injection, 1 x 10 mL vial

**Authority required (STREAMLINED)**

<table>
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<tr>
<th>Authority required</th>
<th>Treatment of AIDS-related Kaposi's sarcoma in patients with CD4 cell counts of less than 200 per cubic millimetre and extensive visceral involvement</th>
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**IMMUNOSTIMULANTS**

**IMMUNOSTIMULANTS**

**Colony stimulating factors**

**FILGRASTIM**

**Authority required (STREAMLINED)**

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<th>Authority required</th>
<th>For use in a patient undergoing induction and consolidation therapy for acute myeloid leukaemia</th>
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**Authority required (STREAMLINED)**

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<th>Mobilisation of peripheral blood progenitor cells to facilitate harvest of such cells for autologous transplantation into a patient with a non-myeloid malignancy who has had myeloablative or myelosuppressive therapy</th>
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**Authority required (STREAMLINED)**

<table>
<thead>
<tr>
<th>Authority required</th>
<th>Mobilisation of peripheral blood progenitor cells, in a normal volunteer, for use in allogeneic transplantation</th>
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**Authority required (STREAMLINED)**

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<th>A patient receiving marrow-ablative chemotherapy and subsequent bone marrow transplantation</th>
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<tbody>
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**Authority required (STREAMLINED)**

<table>
<thead>
<tr>
<th>Authority required</th>
<th>A patient with a non-myeloid malignancy receiving marrow-ablative chemotherapy and subsequent autologous peripheral blood progenitor cell transplantation</th>
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<tbody>
<tr>
<td>3361</td>
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<tr>
<td>Code</td>
<td>Authority required (STREAMLINED)</td>
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<tr>
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</tr>
<tr>
<td>3368</td>
<td>A patient with chronic cyclic neutropenia (absolute neutrophil count of less than 500 million cells per litre lasting for 3 days per cycle, measured over 3 separate cycles, and, either having experienced a life-threatening infectious episode requiring hospitalisation and treatment with intravenous antibiotics, or having recurrent clinically significant infections (a minimum of 3 in the previous 12 months))</td>
</tr>
<tr>
<td>3369</td>
<td>A patient with inoperable Stage III, IVa or IVb squamous cell carcinoma of the oral cavity, larynx, oropharynx or hypopharynx receiving neoadjuvant treatment with docetaxel in combination with cisplatin and fluorouracil who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned</td>
</tr>
<tr>
<td>3362</td>
<td>A patient with breast cancer receiving standard dose adjuvant chemotherapy who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned</td>
</tr>
<tr>
<td>3363</td>
<td>A patient receiving chemotherapy for B-cell chronic lymphocytic leukaemia with fludarabine and cyclophosphamide who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned</td>
</tr>
<tr>
<td>3364</td>
<td>A patient receiving first-line chemotherapy for Hodgkin disease who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned</td>
</tr>
<tr>
<td>3365</td>
<td>A patient receiving chemotherapy for myeloma who has had a prior episode of febrile neutropenia, and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned</td>
</tr>
<tr>
<td>3366</td>
<td>A patient with severe congenital neutropenia (absolute neutrophil count of less than 100 million cells per litre measured on 3 occasions, with readings at least 2 weeks apart, and in whom a bone marrow examination has shown evidence of maturational arrest of the neutrophil lineage)</td>
</tr>
<tr>
<td>3367</td>
<td>A patient with severe chronic neutropenia (absolute neutrophil count of less than 1,000 million cells per litre measured on 3 occasions, with readings at least 2 weeks apart, or evidence of neutrophil dysfunction, and, either having experienced a life-threatening infectious episode requiring hospitalisation and treatment with intravenous antibiotics in the previous 12 months, or having recurrent clinically significant infections (a minimum of 3 in the previous 12 months))</td>
</tr>
<tr>
<td>3370</td>
<td>A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in acute lymphoblastic leukaemia</td>
</tr>
<tr>
<td>3371</td>
<td>A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in breast cancer (adjuvant chemotherapy with docetaxel in combination with an anthracycline and cyclophosphamide)</td>
</tr>
<tr>
<td>3372</td>
<td>A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in germ cell tumours</td>
</tr>
<tr>
<td>3373</td>
<td>A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in infants and children with CNS tumours</td>
</tr>
<tr>
<td>3374</td>
<td>A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in neuroblastoma</td>
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HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

<table>
<thead>
<tr>
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<tr>
<td>3375</td>
<td>A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in non-Hodgkin lymphoma (aggressive grades; or low grade receiving an anthracycline-containing regimen) Authority required (STREAMLINED)</td>
<td>2</td>
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<td>*1006.22</td>
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<td>A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in relapsed Hodgkin disease Authority required (STREAMLINED)</td>
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<td>*2515.54</td>
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LENOGRASTIM
Authority required (STREAMLINED)
3395
Patients with breast cancer receiving standard dose adjuvant chemotherapy who have had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned

Authority required (STREAMLINED)
3396
Patients receiving first-line chemotherapy for Hodgkin's disease who have had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned

Authority required (STREAMLINED)
3392
Mobilisation of peripheral blood progenitor cells to facilitate harvest of such cells for reinfusion into patients with non-myeloid malignancies who have had myeloablative or myelosuppressive therapy

Authority required (STREAMLINED)
3393
Mobilisation of peripheral blood progenitor cells, in normal volunteers, for use in allogeneic transplantation to facilitate harvest of such cells in healthy donors

Authority required (STREAMLINED)
3394
Patients with non-myeloid malignancies receiving marrow-ablative chemotherapy and subsequent peripheral blood progenitor cell or bone marrow transplantation

Authority required (STREAMLINED)
3397
Patients being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in acute lymphoblastic
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<td>Authority required (STREAMLINED)</td>
<td>3401 Patients being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in neuroblastoma</td>
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<td>*2567.20</td>
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<td>PEGFILGRASTIM Authority required (STREAMLINED)</td>
<td>3357 For use in a patient undergoing induction and consolidation therapy for acute myeloid leukaemia</td>
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<tr>
<td>Authority required (STREAMLINED)</td>
<td>3362 A patient with breast cancer receiving standard dose adjuvant chemotherapy who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned</td>
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<tr>
<td>Authority required (STREAMLINED)</td>
<td>3363 A patient receiving chemotherapy for B-cell chronic lymphocytic leukaemia with fludarabine and cyclophosphamide who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned</td>
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<tr>
<td>Authority required (STREAMLINED)</td>
<td>3364 A patient receiving first-line chemotherapy for Hodgkin disease who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned</td>
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<tr>
<td>Authority required (STREAMLINED)</td>
<td>3365 A patient receiving chemotherapy for myeloma who has had a prior episode of febrile neutropenia, and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned</td>
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<tr>
<td>Authority required (STREAMLINED)</td>
<td>3369 A patient with inoperable Stage III, IVa or IVb squamous cell carcinoma of the oral cavity, larynx, oropharynx or hypopharynx receiving neoadjuvant treatment with docetaxel in combination with cisplatin and fluorouracil who has had a prior episode of febrile neutropenia or prolonged severe</td>
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</table>
neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned.

**Authority required (STREAMLINED)**

3370
A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in acute lymphoblastic leukaemia

**Authority required (STREAMLINED)**

3371
A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in breast cancer (adjuvant chemotherapy with docetaxel in combination with an anthracycline and cyclophosphamide)

**Authority required (STREAMLINED)**

3372
A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in germ cell tumours

**Authority required (STREAMLINED)**

3373
A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in infants and children with CNS tumours

**Authority required (STREAMLINED)**

3374
A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in neuroblastoma

**Authority required (STREAMLINED)**

3375
A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in non-Hodgkin lymphoma (aggressive grades; or low grade receiving an anthracycline-containing regimen)

**Authority required (STREAMLINED)**

3376
A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in relapsed Hodgkin disease

**Authority required (STREAMLINED)**

3377
A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in sarcoma

**Authority required (STREAMLINED)**

3834
A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in Hodgkin disease (first-line chemotherapy with escalated BEACOPP)

**Interferons**

**INTERFERON ALFA-2A**

**Authority required (STREAMLINED)**

3382
Use in the treatment of Philadelphia chromosome positive myelogenous leukaemia in the chronic phase

**Authority required (STREAMLINED)**

3961
Chronic hepatitis B in a patient without cirrhosis who satisfies all of the following criteria:

1. Elevated HBV DNA levels - greater than 20,000 IU/mL (100,000 copies/mL) if HBeAg positive, or greater than 2,000 IU/mL (10,000 copies/mL) if HBeAg negative - in conjunction with documented chronic hepatitis B infection;

2. Evidence of chronic liver injury as determined by:
   (a) Confirmed elevated serum ALT; or
   (b) Liver biopsy

**Authority required (STREAMLINED)**

3962
Chronic hepatitis B in a patient with cirrhosis who has detectable HBV DNA.

Persons with Child’s class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy

**Caution**

Treatment with interferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored.
### Interferon Alfa-2B

**Authority required (STREAMLINED) 3384**

Adjunctive therapy of malignant melanoma following surgery in patients with nodal involvement.

**Authority required (STREAMLINED) 3382**

Use in the treatment of Philadelphia chromosome positive myelogenous leukaemia in the chronic phase.

**Authority required (STREAMLINED) 3961**

Chronic hepatitis B in a patient without cirrhosis who satisfies all of the following criteria:

1. Elevated HBV DNA levels - greater than 20,000 IU/mL (100,000 copies/mL) if HBeAg positive, or greater than 2,000 IU/mL (10,000 copies/mL) if HBeAg negative - in conjunction with documented chronic hepatitis B infection;
2. Evidence of chronic liver injury as determined by:
   a. Confirmed elevated serum ALT; or
   b. Liver biopsy.

**Authority required (STREAMLINED) 3962**

Chronic hepatitis B in a patient with cirrhosis who has detectable HBV DNA.

Persons with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy.

**Caution**

Treatment with interferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored.

### Interferon Alfa-2B

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### Interferon Gamma-1B

**Authority required (STREAMLINED) 3985**

Treatment of chronic granulomatous disease in patients with frequent and severe infections despite adequate prophylaxis with antimicrobial agents.

### Peginterferon Alfa-2A

**Authority required (STREAMLINED) 3977**

Treatment, as sole PBS-subsidised therapy, in a patient with chronic hepatitis B without cirrhosis who satisfies all of the following criteria:

1. Elevated HBV DNA levels - greater than 20,000 IU/mL (100,000 copies/mL) if HBeAg positive, or greater than 2,000 IU/mL (10,000 copies/mL) if HBeAg negative - in conjunction with documented chronic hepatitis B infection;
2. Evidence of chronic liver injury as determined by:
   a. Confirmed elevated serum ALT; or
   b. Liver biopsy;
3. Has received no prior peginterferon alfa therapy for the treatment of hepatitis B.
### HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

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<tr>
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<tr>
<td>3978</td>
<td><strong>Treatment, as sole PBS-subsidised therapy, in a patient with chronic hepatitis B with cirrhosis who has detectable HBV DNA.</strong>&lt;br&gt;Persons with Child’s class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy.&lt;br&gt;Treatment is limited to 1 course of treatment for a duration of up to 48 weeks**&lt;br&gt;<strong>Authority required [STREAMLINED]</strong></td>
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<tr>
<td>3412</td>
<td><strong>Treatment, managed by an accredited treatment centre, of chronic hepatitis C in patients 18 years or older who have compensated liver disease and who have received no prior interferon alfa or peginterferon alfa treatment for hepatitis C and have a contraindication to ribavirin, who satisfy all of the following criteria:</strong>&lt;br&gt;(1) Documented chronic hepatitis C infection (repeatedly anti-HCV positive and HCV RNA positive);&lt;br&gt;(2) Female patients of child-bearing age are not pregnant, not breast-feeding, and are using an effective form of contraception.&lt;br&gt;The treatment course is limited to up to 48 weeks.&lt;br&gt;Patients may only continue treatment after the first 12 weeks if the result of an HCV RNA quantitative assay (performed at the same laboratory using the same test) shows that the plasma HCV RNA has become undetectable or the viral load has decreased by at least a 2 log drop**&lt;br&gt;<strong>Caution</strong>&lt;br&gt;Treatment with peginterferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored.**&lt;br&gt;<strong>Note</strong>&lt;br&gt;Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:&lt;br&gt;(a) a nurse educator/counsellor for patients; and&lt;br&gt;(b) 24 hour access by patients to medical advice; and&lt;br&gt;(c) an established liver clinic; and&lt;br&gt;(d) facilities for safe liver biopsy.</td>
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<td>*2700.46</td>
<td>Pegasys RO</td>
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### PEGINTERFERON ALFA-2A (&) RIBAVIRIN

**Authority required [STREAMLINED]**

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<tr>
<td>4184</td>
<td><strong>Chronic genotype 1 hepatitis C infection</strong>&lt;br&gt;<strong>Clinical criteria:</strong>&lt;br&gt;Patient must have compensated liver disease,&lt;br&gt;<strong>AND</strong>&lt;br&gt;Patient must have failed prior treatment with interferon based therapies (non-pegylated or pegylated),&lt;br&gt;<strong>AND</strong>&lt;br&gt;Patient must have received no more than one prior treatment with interferon alfa or peginterferon alfa for hepatitis C if using peginterferon and ribavirin without an NS3 protease inhibitor, or, in triple combination therapy with boceprevir; OR&lt;br&gt;Patient must have received prior treatment with interferon alfa or peginterferon alfa for hepatitis C if using peginterferon and ribavirin in triple combination therapy with telaprevir;&lt;br&gt;<strong>AND</strong>&lt;br&gt;The treatment must be limited to a maximum duration of 24 weeks in patients using peginterferon and ribavirin in triple combination therapy with telaprevir who were prior treatment relapsers and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at weeks 4 and 12; OR&lt;br&gt;The treatment must be limited to a maximum duration of 36 weeks in patients using peginterferon and ribavirin in triple combination therapy with boceprevir who were prior treatment partial responders or relapers and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at weeks 8 and 12; OR&lt;br&gt;The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin without an NS3 protease inhibitor; OR&lt;br&gt;The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin in triple combination therapy with boceprevir who: (i) were prior treatment null responders; or (ii) were prior treatment partial responders or relapers and in whom plasma HCV RNA is detectable by an HCV RNA qualitative assay at week 8, and undetectable by an HCV RNA qualitative assay at week 12; or (iii) have hepatic cirrhosis; OR&lt;br&gt;The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin in triple combination therapy with telaprevir who: (i) were prior treatment partial or null responders; or (ii) were prior treatment relapers and for whom the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is detectable but less than or equal to 1000 IU/mL; or (iii) have hepatic cirrhosis,</td>
<td></td>
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AND

The treatment must cease in patients using peginterferon and ribavirin without an NS3 protease inhibitor if HCV RNA is detectable by an HCV RNA qualitative assay at week 12.

AND

The treatment must cease in patients using peginterferon and ribavirin in combination with boceprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12.

AND

The treatment must cease in patients using peginterferon and ribavirin in combination with boceprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24.

AND

The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is greater than 1000 IU/ml.

AND

The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12.

AND

The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24.

Population criteria:

Patient must be aged 18 years or older,

AND

Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

Treatment criteria:

Must be treated in an accredited treatment centre.

Evidence of chronic genotype 1 hepatitis C infection (repeatedly anti-HCV positive and HCV RNA positive) must be documented in the patient’s medical records.

Note

No increase in the maximum quantity or number of units may be authorised.

Note

No increase in the maximum number of repeats may be authorised.

Note

Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:

(a) a nurse educator/counsellor for patients; and
(b) 24-hour access by patients to medical advice; and
(c) an established liver clinic.

Authority required (STREAMLINED)

4197

Chronic genotype 1 hepatitis C infection

Clinical criteria:

Patient must have compensated liver disease,

AND

Patient must not have received prior interferon alfa or peginterferon alfa treatment for hepatitis C,

AND

The treatment must be limited to a maximum duration of 24 weeks in patients using peginterferon and ribavirin in triple combination therapy with telaprevir and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at weeks 4 and 12; OR

The treatment must be limited to a maximum duration of 28 weeks in patients using peginterferon and ribavirin in triple combination therapy with boceprevir and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at weeks 8 and 24; OR

The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin without an NS3 protease inhibitor; OR

The treatment must be limited to a maximum duration of 48 weeks in patients: (i) using peginterferon and ribavirin in triple combination therapy with boceprevir and in whom plasma HCV RNA is detectable by an HCV RNA qualitative assay at week 8, and undetectable by an HCV RNA qualitative assay at week 24; or (ii) using peginterferon and ribavirin in triple combination therapy with boceprevir who have hepatic cirrhosis; OR

The treatment must be limited to a maximum duration of 48 weeks in patients: (i) using peginterferon and ribavirin in triple combination therapy with telaprevir and for whom the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is detectable but less than or
equal to 1000 IU/mL; or (ii) using peginterferon and ribavirin in triple combination therapy with telaprevir who have hepatic cirrhosis,

AND

The treatment must cease in patients using peginterferon and ribavirin without an NS3 protease inhibitor unless the results of an HCV RNA quantitative assay at week 12 (performed at the same laboratory using the same test) show that plasma HCV RNA has become undetectable or the viral load has decreased by at least a 2 log drop,

AND

The treatment must cease in patients using peginterferon and ribavirin in combination with boceprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 4 show that the plasma HCV RNA is greater than 1000 IU/mL.

AND

The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if the results of an HCV RNA qualitative assay at week 4 show that the plasma HCV RNA is greater than 1000 IU/mL.

AND

The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12.

AND

The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24.

Population criteria:
Patient must be aged 18 years or older,

AND

Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

Treatment criteria:
Must be treated in an accredited treatment centre.

Evidence of chronic hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.

For patients using peginterferon and ribavirin without an NS3 protease inhibitor who are viral negative at week 12, an HCV RNA qualitative assay at week 24 is unnecessary.

Note
No increase in the maximum quantity or number of units may be authorised.

Note
No increase in the maximum number of repeats may be authorised.

Note
Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:

(a) a nurse educator/counsellor for patients; and
(b) 24-hour access by patients to medical advice; and
(c) an established liver clinic.

Authority required (STREAMLINED)

4206
Chronic non-genotype 1 hepatitis C infection

Clinical criteria:
The treatment must be the sole PBS-subsidised treatment for hepatitis C,

AND

Patient must have compensated liver disease,

AND

The condition must be genotype 2, 3, 4, 5 or 6 hepatitis C,

AND

Patient must have failed prior treatment with interferon based therapies (non-pegylated or pegylated),

AND

Patient must have received no more than one prior treatment with interferon alfa or peginterferon alfa for hepatitis C,

AND

The treatment must be limited to a maximum duration of 48 weeks,

AND

The treatment must cease if HCV RNA is detectable by an HCV RNA qualitative assay at week 12.
### HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

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**Population criteria:**
Patient must be aged 18 years or older, AND
Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

**Treatment criteria:**
Must be treated in an accredited treatment centre.

Evidence of chronic hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.

**Note**
No increase in the maximum quantity or number of units may be authorised.

**Note**
No increase in the maximum number of repeats may be authorised.

**Note**
Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:
(a) a nurse educator/counsellor for patients; and
(b) 24-hour access by patients to medical advice; and
(c) an established liver clinic.

**Authority required (STREAMLINED)**

4187
Chronic non-genotype 1 hepatitis C infection

**Clinical criteria:**
The treatment must be the sole PBS-subsidised treatment for hepatitis C, AND
Patient must have compensated liver disease, AND
Patient must not have received prior interferon alfa or peginterferon alfa treatment for hepatitis C, AND
The condition must be genotype 2, 3, 4, 5 or 6 hepatitis C, AND
The treatment must be limited to a maximum duration of 24 weeks for patients with genotype 2 or 3 hepatitis C without hepatic cirrhosis or bridging fibrosis; OR
The treatment must be limited to a maximum duration of 48 weeks for patients with genotype 4, 5 or 6 hepatitis C; OR
The treatment must be limited to a maximum duration of 48 weeks for patients with genotype 2 or 3 hepatitis C with hepatic cirrhosis or bridging fibrosis, AND
The treatment must cease in patients with genotype 4, 5, or 6 hepatitis C unless the results of an HCV RNA quantitative assay at week 12 (performed at the same laboratory using the same test) shows that plasma HCV RNA has become undetectable or the viral load has decreased by at least a 2 log drop, AND
The treatment must cease in patients eligible for 48 weeks of treatment if HCV RNA is detectable by an HCV RNA qualitative assay at week 24.

**Population criteria:**
Patient must be aged 18 years or older, AND
Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

**Treatment criteria:**
Must be treated in an accredited treatment centre.

Evidence of chronic hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records. For patients with genotype 4, 5, or 6 who are viral negative at week 12, an HCV RNA qualitative assay at week 24 is unnecessary. For patients with genotype 2 or 3 without cirrhosis, an HCV RNA assay at week 12 is unnecessary because of the high likelihood of early viral response by week 12. For patients who are eligible for 24 weeks of treatment, a maximum of 2 repeats may be prescribed. For patients who are eligible for 48 weeks of treatment, a maximum of 5 repeats may be prescribed.
### HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

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<td>*3406.36</td>
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**PEGINTERFERON ALFA-2B (&) RIBAVIRIN**

**Authority required (STREAMLINED)**

4189 Chronic genotype 1 hepatitis C infection

**Clinical criteria:**

The treatment must be the sole PBS-subsidised treatment for hepatitis C,

AND

Patient must have compensated liver disease,

AND

Patient must have failed prior treatment with interferon based therapies (non-pegylated or pegylated),

AND

Patient must have received no more than one prior treatment with interferon alfa or peginterferon alfa for hepatitis C,

AND

The treatment must be limited to a maximum duration of 48 weeks,

AND

The treatment must cease if HCV RNA is detectable by an HCV RNA qualitative assay at week 12.

**Population criteria:**

Patient must weigh at least 27 kg,

AND

Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

**Treatment criteria:**

Must be treated in an accredited treatment centre.

Evidence of chronic genotype 1 hepatitis C infection (repeatedly anti-HCV positive and HCV RNA positive) must be documented in the patient’s medical records.

**Note**

No increase in the maximum quantity or number of units may be authorised.

**Note**

No increase in the maximum number of repeats may be authorised.

**Note**

Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:

(a) a nurse educator/counsellor for patients; and
### Chronic genotype 1 hepatitis C infection

**Clinical criteria:**
- The treatment must be the sole PBS-subsidised treatment for hepatitis C,
- Patient must have compensated liver disease,
- Patient must not have received prior interferon alfa or peginterferon alfa treatment for hepatitis C,
- The treatment must be limited to a maximum duration of 48 weeks,
- The treatment must cease unless the results of an HCV RNA quantitative assay at week 12 (performed at the same laboratory using the same test) show that plasma HCV RNA has become undetectable or the viral load has decreased by at least a 2 log drop.

**Population criteria:**
- Patient must weigh at least 27 kg,
- Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

**Treatment criteria:**
- Must be treated in an accredited treatment centre.
- Evidence of chronic hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient’s medical records.
- For patients who are viral negative at week 12, an HCV RNA qualitative assay at week 24 is unnecessary.

**Note**
- No increase in the maximum quantity or number of units may be authorised.
- No increase in the maximum number of repeats may be authorised.

**Note**
- Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:
  - (a) a nurse educator/counsellor for patients; and
  - (b) 24-hour access by patients to medical advice; and
  - (c) an established liver clinic.

### Chronic non-genotype 1 hepatitis C infection

**Clinical criteria:**
- The treatment must be the sole PBS-subsidised treatment for hepatitis C,
- Patient must have compensated liver disease,
- The condition must be genotype 2, 3, 4, 5 or 6 hepatitis C,
- Patient must have failed prior treatment with interferon based therapies (non-pegylated or pegylated),
- Patient must have received no more than one prior treatment with interferon alfa or peginterferon alfa for hepatitis C,
- The treatment must be limited to a maximum duration of 48 weeks,
- The treatment must cease if HCV RNA is detectable by an HCV RNA qualitative assay at week 12.

**Population criteria:**
Patient must weigh at least 27 kg.

AND

Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

Treatment criteria:
Must be treated in an accredited treatment centre.

Evidence of chronic hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.

Note
No increase in the maximum quantity or number of units may be authorised.

Note
No increase in the maximum number of repeats may be authorised.

Note
Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:
(a) a nurse educator/counsellor for patients; and
(b) 24-hour access by patients to medical advice; and
(c) an established liver clinic.

Authority required (STREAMLINED)
4192
Chronic non-genotype 1 hepatitis C infection

Clinical criteria:
The treatment must be the sole PBS-subsidised treatment for hepatitis C,

AND

Patient must have compensated liver disease,

AND

Patient must not have received prior interferon alfa or peginterferon alfa treatment for hepatitis C,

AND

The condition must be genotype 2, 3, 4, 5 or 6 hepatitis C,

AND

The treatment must be limited to a maximum duration of 24 weeks for patients with genotype 2 or 3 hepatitis C without hepatic cirrhosis or bridging fibrosis; OR
The treatment must be limited to a maximum duration of 48 weeks for patients with genotype 4, 5 or 6 hepatitis C; OR
The treatment must be limited to a maximum duration of 48 weeks for patients with genotype 2 or 3 hepatitis C with hepatic cirrhosis or bridging fibrosis,

AND

The treatment must cease in patients with genotype 4, 5, or 6 hepatitis C unless the results of an HCV RNA quantitative assay at week 12 (performed at the same laboratory using the same test) shows that plasma HCV RNA has become undetectable or the viral load has decreased by at least a 2 log drop,

AND

The treatment must cease in patients eligible for 48 weeks of treatment if HCV RNA is detectable by an HCV RNA qualitative assay at week 24.

Population criteria:
Patient must weigh at least 27 kg.

AND

Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

Treatment criteria:
Must be treated in an accredited treatment centre.

Evidence of chronic hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.

For patients with genotype 4, 5, or 6 who are viral negative at week 12, an HCV RNA qualitative assay at week 24 is unnecessary.

For patients with genotype 2 or 3 without cirrhosis, an HCV RNA assay at week 12 is unnecessary because of the high likelihood of early viral response by week 12.

For patients who are eligible for 24 weeks of treatment, a maximum of 2 repeats may be prescribed.

For patients who are eligible for 48 weeks of treatment, a maximum of 5 repeats may be prescribed.

Note
### Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:

(a) a nurse educator/counsellor for patients; and  
(b) 24-hour access by patients to medical advice; and  
(c) an established liver clinic.

### Authority required (STREAMLINED)

**4184**  
Chronic genotype 1 hepatitis C infection

**Clinical criteria:**

Patient must have compensated liver disease,

**AND**  
Patient must have failed prior treatment with interferon based therapies (non-pegylated or pegylated),

**AND**  
Patient must have received no more than one prior treatment with interferon alfa or peginterferon alfa for hepatitis C if using peginterferon and ribavirin without an NS3 protease inhibitor, or, in triple combination therapy with boceprevir; OR  
Patient must have received prior treatment with interferon alfa or peginterferon alfa for hepatitis C if using peginterferon and ribavirin in triple combination therapy with telaprevir,

**AND**  
The treatment must be limited to a maximum duration of 24 weeks in patients using peginterferon and ribavirin in triple combination therapy with telaprevir who were prior treatment relapers and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at weeks 4 and 12; OR  
The treatment must be limited to a maximum duration of 36 weeks in patients using peginterferon and ribavirin in triple combination therapy with boceprevir who were prior treatment partial responders or relapers and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at weeks 8 and 12; OR  
The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin without an NS3 protease inhibitor; OR  
The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin in triple combination therapy with boceprevir who: (i) were prior treatment null responders; or (ii) were prior treatment partial responders or relapers and in whom plasma HCV RNA is detectable by an HCV RNA qualitative assay at week 8, and undetectable by an HCV RNA qualitative assay at week 12; or (iii) have hepatic cirrhosis; OR  
The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin in triple combination therapy with telaprevir who: (i) were prior treatment partial or null responders; or (ii) were prior treatment relapers and for whom the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is detectable but less than or equal to 1000 IU/mL; or (iii) have hepatic cirrhosis,

**AND**  
The treatment must cease in patients using peginterferon and ribavirin without an NS3 protease inhibitor if HCV RNA is detectable by an HCV RNA qualitative assay at week 12.

**AND**  
The treatment must cease in patients using peginterferon and ribavirin in combination with boceprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12.

**AND**  
The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12.

**AND**  
The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is greater than 1000 IU/mL.

**AND**  
The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24.

**Population criteria:**

Patient must be aged 18 years or older,

**AND**  
Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

**Treatment criteria:**
HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

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Must be treated in an accredited treatment centre.

Evidence of chronic genotype 1 hepatitis C infection (repeatedly anti-HCV positive and HCV RNA positive) must be documented in the patient’s medical records.

**Note**
No increase in the maximum quantity or number of units may be authorised.

**Note**
No increase in the maximum number of repeats may be authorised.

**Note**
Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:

(a) a nurse educator/counsellor for patients; and

(b) 24-hour access by patients to medical advice; and

(c) an established liver clinic.

**Authority required (STREAMLINED)**

4197

Chronic genotype 1 hepatitis C infection

**Clinical criteria:**

Patient must have compensated liver disease,

AND

Patient must not have received prior interferon alfa or peginterferon alfa treatment for hepatitis C,

AND

The treatment must be limited to a maximum duration of 24 weeks in patients using peginterferon and ribavirin in triple combination therapy with telaprevir and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at weeks 4 and 12; OR

The treatment must be limited to a maximum duration of 28 weeks in patients using peginterferon and ribavirin in triple combination therapy with boceprevir and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at weeks 8 and 24; OR

The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin without an NS3 protease inhibitor; OR

The treatment must be limited to a maximum duration of 48 weeks in patients: (i) using peginterferon and ribavirin in triple combination therapy with boceprevir and in whom plasma HCV RNA is detectable by an HCV RNA qualitative assay at week 8, and undetectable by an HCV RNA qualitative assay at week 24; OR

The treatment must be limited to a maximum duration of 48 weeks in patients: (i) using peginterferon and ribavirin in triple combination therapy with telaprevir and for whom the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is detectable but less than or equal to 1000 IU/mL; or (ii) using peginterferon and ribavirin in triple combination therapy with telaprevir who have hepatic cirrhosis; OR

AND

The treatment must cease in patients using peginterferon and ribavirin without an NS3 protease inhibitor unless the results of an HCV RNA quantitative assay at week 12 (performed at the same laboratory using the same test) show that plasma HCV RNA has become undetectable or the viral load has decreased by at least a 2 log drop,

AND

The treatment must cease in patients using peginterferon and ribavirin in combination with boceprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24,

AND

The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is greater than 1000 IU/mL,

AND

The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12,

AND

The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24.

**Population criteria:**

Patient must be aged 18 years or older,

AND

Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

**Treatment criteria:**

Must be treated in an accredited treatment centre.
Evidence of chronic hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient’s medical records.

For patients using peginterferon and ribavirin without an NS3 protease inhibitor who are viral negative at week 12, an HCV RNA qualitative assay at week 24 is unnecessary.

**Note**
No increase in the maximum quantity or number of units may be authorised.

**Note**
No increase in the maximum number of repeats may be authorised.

**Note**
Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:
(a) a nurse educator/counsellor for patients; and
(b) 24-hour access by patients to medical advice; and
(c) an established liver clinic.

**Authority required (STREAMLINED)**

4206
Chronic non-genotype 1 hepatitis C infection

**Clinical criteria:**
The treatment must be the sole PBS-subsidised treatment for hepatitis C,
AND
Patient must have compensated liver disease,
AND
The condition must be genotype 2, 3, 4, 5 or 6 hepatitis C,
AND
Patient must have failed prior treatment with interferon based therapies (non-pegylated or pegylated),
AND
Patient must have received no more than one prior treatment with interferon alfa or peginterferon alfa for hepatitis C,
AND
The treatment must be limited to a maximum duration of 48 weeks,
AND
The treatment must cease if HCV RNA is detectable by an HCV RNA qualitative assay at week 12.

**Population criteria:**
Patient must be aged 18 years or older,
AND
Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

**Treatment criteria:**
Must be treated in an accredited treatment centre.

Evidence of chronic hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient’s medical records.

**Note**
No increase in the maximum quantity or number of units may be authorised.

**Note**
No increase in the maximum number of repeats may be authorised.

**Note**
Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:
(a) a nurse educator/counsellor for patients; and
(b) 24-hour access by patients to medical advice; and
(c) an established liver clinic.

**Authority required (STREAMLINED)**

4187
Chronic non-genotype 1 hepatitis C infection

**Clinical criteria:**
The treatment must be the sole PBS-subsidised treatment for hepatitis C,
AND
Patient must have compensated liver disease, AND Patient must not have received prior interferon alfa or peginterferon alfa treatment for hepatitis C, AND The condition must be genotype 2, 3, 4, 5 or 6 hepatitis C, AND The treatment must be limited to a maximum duration of 24 weeks for patients with genotype 2 or 3 hepatitis C without hepatic cirrhosis or bridging fibrosis; OR The treatment must be limited to a maximum duration of 48 weeks for patients with genotype 4, 5 or 6 hepatitis C; OR The treatment must be limited to a maximum duration of 48 weeks for patients with genotype 2 or 3 hepatitis C with hepatic cirrhosis or bridging fibrosis, AND The treatment must cease in patients with genotype 4, 5, or 6 hepatitis C unless the results of an HCV RNA quantitative assay at week 12 (performed at the same laboratory using the same test) shows that plasma HCV RNA has become undetectable or the viral load has decreased by at least a 2 log drop, AND The treatment must cease in patients eligible for 48 weeks of treatment if HCV RNA is detectable by an HCV RNA qualitative assay at week 24. Population criteria: Patient must be aged 18 years or older, AND Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age. Treatment criteria: Must be treated in an accredited treatment centre. Evidence of chronic hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records. For patients with genotype 4, 5, or 6 who are viral negative at week 12, an HCV RNA qualitative assay at week 24 is unnecessary. For patients with genotype 2 or 3 without cirrhosis, an HCV RNA assay at week 12 is unnecessary because of the high likelihood of early viral response by week 12. For patients who are eligible for 24 weeks of treatment, a maximum of 2 repeats may be prescribed. For patients who are eligible for 48 weeks of treatment, a maximum of 5 repeats may be prescribed. Caution Treatment with peginterferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored. Caution Ribavirin is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and during the 6 months period after cessation of treatment. Note Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C: (a) a nurse educator/counsellor for patients; and (b) 24-hour access by patients to medical advice; and (c) an established liver clinic.
Chronic genotype 1 hepatitis C infection

Clinical criteria:

Patient must have compensated liver disease,

AND

Patient must have failed prior treatment with interferon based therapies (non-pegylated or pegylated),

AND

Patient must have received no more than one prior treatment with interferon alfa or peginterferon alfa for hepatitis C if using peginterferon and ribavirin without an NS3 protease inhibitor, or, in triple combination therapy with boceprevir; OR

Patient must have received prior treatment with interferon alfa or peginterferon alfa for hepatitis C if using peginterferon and ribavirin in triple combination therapy with telaprevir;

AND

The treatment must be limited to a maximum duration of 24 weeks in patients using peginterferon and ribavirin in triple combination therapy with telaprevir who were prior treatment relapsers and in whose plasma HCV RNA is undetectable by an HCV RNA qualitative assay at weeks 4 and 12; OR

The treatment must be limited to a maximum duration of 36 weeks in patients using peginterferon and ribavirin in triple combination therapy with boceprevir who were prior treatment partial responders or relapsers and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at weeks 8 and 12; OR

The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin without an NS3 protease inhibitor; OR

The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin in triple combination therapy with boceprevir who: (i) were prior treatment null responders; or (ii) were prior treatment partial responders or relapsers and for whom the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is detectable but less than or equal to 1000 IU/mL; or (iii) have hepatic cirrhosis, OR

The treatment must cease in patients using peginterferon and ribavirin without an NS3 protease inhibitor if HCV RNA is detectable by an HCV RNA qualitative assay at week 12,

AND

The treatment must cease in patients using peginterferon and ribavirin in combination with boceprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24,

AND

The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is detectable but less than 1000 IU/mL,

AND

The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12,

AND

The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24.

Population criteria:

Patient must be aged 18 years or older,

AND

Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

Treatment criteria:

Must be treated in an accredited treatment centre.

Evidence of chronic genotype 1 hepatitis C infection (repeatedly anti-HCV positive and HCV RNA positive) must be documented in the patient’s medical records.

Note

No increase in the maximum quantity or number of units may be authorised.

Note

No increase in the maximum number of repeats may be authorised.
### Note
Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:

(a) a nurse educator/counsellor for patients; and

(b) 24-hour access by patients to medical advice; and

(c) an established liver clinic.

### Authority required (STREAMLINED)

4197

Chronic genotype 1 hepatitis C infection

#### Clinical criteria:

Patient must have compensated liver disease,

**AND**

Patient must not have received prior interferon alfa or peginterferon alfa treatment for hepatitis C,

**AND**

The treatment must be limited to a maximum duration of 24 weeks in patients using peginterferon and ribavirin in triple combination therapy with telaprevir and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at weeks 4 and 12; OR

The treatment must be limited to a maximum duration of 28 weeks in patients using peginterferon and ribavirin in triple combination therapy with boceprevir and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at weeks 8 and 24; OR

The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin without an NS3 protease inhibitor; OR

The treatment must be limited to a maximum duration of 48 weeks in patients: (i) using peginterferon and ribavirin in triple combination therapy with boceprevir and in whom plasma HCV RNA is detectable by an HCV RNA qualitative assay at week 8, and undetectable by an HCV RNA qualitative assay at week 24; or (ii) using peginterferon and ribavirin in triple combination therapy with boceprevir who have hepatic cirrhosis; OR

The treatment must be limited to a maximum duration of 48 weeks in patients: (i) using peginterferon and ribavirin in triple combination therapy with telaprevir and for whom the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is detectable but less than or equal to 1000 IU/mL; or (ii) using peginterferon and ribavirin in triple combination therapy with telaprevir who have hepatic cirrhosis,

**AND**

The treatment must cease in patients using peginterferon and ribavirin without an NS3 protease inhibitor unless the results of an HCV RNA quantitative assay at week 12 (performed at the same laboratory using the same test) show that plasma HCV RNA has become undetectable or the viral load has decreased by at least a 2 log drop,

**AND**

The treatment must cease in patients using peginterferon and ribavirin in combination with boceprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24,

**AND**

The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is greater than 1000 IU/mL,

**AND**

The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24.

**Population criteria:**

Patient must be aged 18 years or older,

**AND**

Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

**Treatment criteria:**

Must be treated in an accredited treatment centre.

Evidence of chronic hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.

For patients using peginterferon and ribavirin without an NS3 protease inhibitor who are viral negative at week 12, an HCV RNA qualitative assay at week 24 is unnecessary.

**Note**

No increase in the maximum quantity or number of units may be authorised.

**Note**

No increase in the maximum number of repeats may be authorised.
Note
Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:

(a) a nurse educator/counsellor for patients; and
(b) 24-hour access by patients to medical advice; and
(c) an established liver clinic.

Authority required (STREAMLINED)
4206
Chronic non-genotype 1 hepatitis C infection

Clinical criteria:
The treatment must be the sole PBS-subsidised treatment for hepatitis C,

AND

Patient must have compensated liver disease,

AND

The condition must be genotype 2, 3, 4, 5 or 6 hepatitis C,

AND

Patient must have failed prior treatment with interferon based therapies (non-pegylated or pegylated),

AND

Patient must have received no more than one prior treatment with interferon alfa or peginterferon alfa for hepatitis C,

AND

The treatment must be limited to a maximum duration of 48 weeks,

AND

The treatment must cease if HCV RNA is detectable by an HCV RNA qualitative assay at week 12.

Population criteria:
Patient must be aged 18 years or older,

AND

Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

Treatment criteria:
Must be treated in an accredited treatment centre.

Evidence of chronic hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient’s medical records.

Note
No increase in the maximum quantity or number of units may be authorised.

Note
No increase in the maximum number of repeats may be authorised.

Note
Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:

(a) a nurse educator/counsellor for patients; and
(b) 24-hour access by patients to medical advice; and
(c) an established liver clinic.

Authority required (STREAMLINED)
4187
Chronic non-genotype 1 hepatitis C infection

Clinical criteria:
The treatment must be the sole PBS-subsidised treatment for hepatitis C,

AND

Patient must have compensated liver disease,

AND

Patient must not have received prior interferon alfa or peginterferon alfa treatment for hepatitis C,

AND

The condition must be genotype 2, 3, 4, 5 or 6 hepatitis C.
The treatment must be limited to a maximum duration of 24 weeks for patients with genotype 2 or 3 hepatitis C without hepatic cirrhosis or bridging fibrosis; OR

The treatment must be limited to a maximum duration of 48 weeks for patients with genotype 4, 5 or 6 hepatitis C; OR

The treatment must be limited to a maximum duration of 48 weeks for patients with genotype 2 or 3 hepatitis C with hepatic cirrhosis or bridging fibrosis,

AND

The treatment must cease in patients with genotype 4, 5, or 6 hepatitis C unless the results of an HCV RNA quantitative assay at week 12 (performed at the same laboratory using the same test) shows that plasma HCV RNA has become undetectable or the viral load has decreased by at least a 2 log drop,

AND

The treatment must cease in patients eligible for 48 weeks of treatment if HCV RNA is detectable by an HCV RNA qualitative assay at week 24.

Population criteria:

Patient must be aged 18 years or older,

AND

Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

Treatment criteria:

Must be treated in an accredited treatment centre.

Evidence of chronic hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient’s medical records.

For patients with genotype 4, 5, or 6 who are viral negative at week 12, an HCV RNA qualitative assay at week 24 is unnecessary.

For patients with genotype 2 or 3 without cirrhosis, an HCV RNA assay at week 12 is unnecessary because of the high likelihood of early viral response by week 12.

For patients who are eligible for 24 weeks of treatment, a maximum of 2 repeats may be prescribed.

For patients who are eligible for 48 weeks of treatment, a maximum of 5 repeats may be prescribed.

Caution

Treatment with peginterferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored.

Caution

Ribavirin is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and during the 6 months period after cessation of treatment.

Note

Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:

(a) a nurse educator/counsellor for patients; and

(b) 24-hour access by patients to medical advice; and

(c) an established liver clinic.

9536X peginterferon alfa-2b 120 microgram injection [4 x 120 microgram cartridges] & ribavirin 200 mg capsule [140 capsules] & inert substance diluent [4 x 0.5 mL cartridges], 1 pack

9538B peginterferon alfa-2b 150 microgram injection [4 x 150 microgram cartridges] & ribavirin 200 mg capsule [140 capsules] & inert substance diluent [4 x 0.5 mL cartridges], 1 pack

9539C peginterferon alfa-2b 150 microgram injection [4 x 150 microgram cartridges] & ribavirin 200 mg capsule [168 capsules] & inert substance diluent [4 x 0.5 mL cartridges], 1 pack

9540D peginterferon alfa-2b 150 microgram injection [4 x 150 microgram cartridges] & ribavirin 200 mg capsule [196 capsules] & inert substance diluent [4 x 0.5 mL cartridges], 1 pack

9531P peginterferon alfa-2b 80 microgram injection [4 x 80 microgram cartridges] & ribavirin 200 mg capsule [140 capsules] & inert substance diluent [4 x 0.5 mL cartridges], 1 pack

Other immunostimulants

PLERIXAFOR

Authority required (STREAMLINED)

4549
**HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)**

<table>
<thead>
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<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>Dispensed Price for Max. Qty $</th>
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<td></td>
<td>Mobilisation of haematopoietic stem cells</td>
<td></td>
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<td></td>
<td>Clinical criteria:</td>
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<td></td>
<td>The treatment must be in combination with granulocyte-colony stimulating factor (G-CSF), AND</td>
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<td>Patient must have lymphoma; OR</td>
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<td></td>
<td>Patient must have multiple myeloma, AND</td>
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<td></td>
<td>Patient must require autologous stem cell transplantation, AND</td>
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<td></td>
<td>Patient must have failed previous stem cell collection; OR</td>
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<td></td>
<td>Patient must be undergoing chemotherapy plus G-CSF mobilisation and their peripheral blood CD34+ count is less than 10,000 per millilitre or less than 10 million per litre on the day of planned collection; OR</td>
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<tr>
<td></td>
<td>Patient must be undergoing chemotherapy plus G-CSF mobilisation and the first apheresis has yielded less than 1 million CD34+ cells/kg.</td>
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<td>Evidence that the patient meets the PBS restriction criteria must be recorded in the patient’s medical records.</td>
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<td>Note Applications for increased maximum quantities will only be authorised for patients with body weight greater than 100 kg.</td>
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<td>6991.00</td>
<td>Mozobil GZ</td>
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**IMMUNOSUPPRESSANTS**

**Selective immunosuppressants**

**ABATACEPT**

**Authority required**

Initial 1 (new patient or patient re-commencing after a break of more than 24 months)

Initial PBS-subsidised treatment with abatacept, in combination with methotrexate at a dose of at least 7.5 mg weekly, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults who:

(a) have severe active rheumatoid arthritis; and
(b) have received no PBS-subsidised treatment with a bDMARD for this condition in the previous 24 months; and
(c) have failed, in the 24 months immediately prior to the date of application, to achieve an adequate response to at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs), which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be:

— hydroxychloroquine at a dose of at least 200 mg daily; or
— leflunomide at a dose of at least 10 mg daily; or
— sulfasalazine at a dose of at least 2 g daily.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, then the 6 months of intensive DMARD treatment must include at least 3 months continuous treatment with each of at least 2 of the DMARDs:

— hydroxychloroquine at a dose of at least 200 mg daily; and/or
— leflunomide at a dose of at least 10 mg daily; and/or
— sulfasalazine at a dose of at least 2 g daily.

The application must include details of the contraindication or intolerance to methotrexate. Details of the toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose can be found on the Medicare Australia website [www.medicareaustralia.gov.au]. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

If 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved product information or cannot be tolerated at the doses specified above, then one or more of the following DMARDs may be used in place of these agents in order to satisfy the requirement for a trial of 6 months of intensive DMARD therapy with at least 2 DMARDs taken continuously for at least 3 months each:

— azathioprine at a dose of at least 1 mg/kg per day; and/or
— cyclosporin at a dose of at least 2 mg/kg/day; and/or
— sodium aurothiomalate at a dose of 50 mg weekly.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances. Details of the toxicities, including severity, which will be accepted as a reason for substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial can be found on the Medicare Australia website.
The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance and dose for each DMARD must be provided in the authority application. Details of the toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy can be found on the Medicare Australia website [www.medicareaustralia.gov.au].

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

- an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L;
- AND either
  - (i) a total active joint count of at least 20 active (swollen and tender) joints; or
  - (ii) at least 4 active joints from the following list of major joints:
    - elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
    - shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the retention in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

1. A completed authority prescription form; and
2. A completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website [www.medicareaustralia.gov.au]]; and
3. A signed patient acknowledgement.

A maximum of 16 weeks of treatment will be authorised under this restriction.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion. Up to a maximum of 4 repeats may be authorised. Where fewer than 4 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Assessment of a patient’s response to an initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with abatacept.

Patients who fail to demonstrate a response to treatment with abatacept under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition

**Authority required**

Initial 2 (change or re-commencement after break of less than 24 months)

Initial course of PBS-subsidised treatment with abatacept, in combination with methotrexate at a dose of at least 7.5 mg weekly, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults who:

1. have a documented history of severe active rheumatoid arthritis; and
2. have received prior PBS-subsidised bDMARD treatment for this condition and are eligible to receive further bDMARD therapy.

The authority application must be made in writing and must include:

1. A completed authority prescription form; and
2. A completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website [www.medicareaustralia.gov.au]].

Applications for patients who have received PBS-subsidised treatment with abatacept and who wish to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient’s most recent course of PBS-subsidised abatacept treatment, within the timeframes specified below.

A maximum of 16 weeks of treatment will be authorised under this restriction.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion. Up to a maximum of 4 repeats may be authorised.
Where fewer than 4 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Where the most recent course of PBS-subsidised abatacept treatment was approved under either of the initial 1 or 2 treatment restrictions, patients must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be provided to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised abatacept treatment was approved under the continuing treatment criteria, patients must have been assessed for response, and the assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Patients who fail to demonstrate a response to treatment with abatacept under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition

**Authority required**

Continuing treatment

Continuing PBS-subsidised treatment with abatacept, in combination with methotrexate at a dose of at least 7.5 mg weekly, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults:

(a) who have a documented history of severe active rheumatoid arthritis; and

(b) who have demonstrated an adequate response to treatment with abatacept; and

(c) whose most recent course of PBS-subsidised bDMARD treatment was with abatacept.

An adequate response to treatment is defined as:

- an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

- (i) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

- (ii) a reduction in the number of the following major active joints, from at least 4, by at least 50%:
  - elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
  - shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The authority application must be made in writing and must include:

1. a completed authority prescription form; and

2. a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

A maximum of 24 weeks of treatment will be approved under this restriction.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion. Up to a maximum of 5 repeats may be authorised.

Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

All applications for continuing treatment with abatacept must include a measurement of response to the prior course of therapy. This assessment must be provided to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with abatacept, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

Patients who fail to demonstrate a response to treatment with abatacept under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition

**Note**

Any queries concerning the arrangements to prescribe abatacept may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Further prescribing information (including Authority Application Forms) is on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe abatacept should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

**Note**

**TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying anti-rheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further that agent (Initial 2).

(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uni

For second and subsequent courses of PBS-

respond to treatment with that bDMARD.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-

(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or

(iii) a patient has received prior PBS-subsidised therapy with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

PBS-subsidised abatacept, golimumab, infliximab and rituximab must be used in combination with methotrexate at a dose of at least 7.5 mg weekly. Where a patient cannot tolerate 7.5 mg of methotrexate weekly, they are eligible to receive PBS-subsidised adalimumab, certolizumab pegol, etanercept and tocilizumab.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:

— a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,

— a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and

— once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact Medicare Australia on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or

(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or

(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or

(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab and tocilizumab, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to Medicare Australia within 4 weeks.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:

Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient’s weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:

A further application may be submitted to Medicare Australia 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.
Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept patients:

Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

Note

(3) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and Medicare Australia will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Note

Special Pricing Arrangements apply.

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
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<th>Brand Name and Manufacturer</th>
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EVEROLIMUS

Authority required (STREAMLINED)

3355

Management of rejection, under the supervision and direction of a transplant unit, in patients receiving this drug for prophylaxis of renal allograft rejection. Management includes initiation, stabilisation and review of therapy as required

Authority required (STREAMLINED)

3356

Management of rejection, under the supervision and direction of a transplant unit, in patients receiving this drug for prophylaxis of cardiac allograft rejection. Management includes initiation, stabilisation and review of therapy as required

Caution
HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
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<td>5740D</td>
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<td>5</td>
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</tbody>
</table>

MYCOPHENOLATE

**Authority required (STREAMLINED)**

4084 Prophylaxis of renal allograft rejection

**Clinical criteria:**

The treatment must be under the supervision and direction of a transplant unit.

**Authority required (STREAMLINED)**

4095 WHO Class III, IV or V lupus nephritis

**Clinical criteria:**

The condition must be proven by biopsy.

**Treatment criteria:**

Must be treated by a nephrologist or in consultation with a nephrologist.

The name of the consulting nephrologist must be included in the patient medical records.

**Caution**

Careful monitoring of patients is mandatory.

**Note**

Management includes initiation, stabilisation and review of therapy as required.

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
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<td>5</td>
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MYCOPHENOLATE

**Authority required (STREAMLINED)**

3355 Management of rejection, under the supervision and direction of a transplant unit, in patients receiving this drug for prophylaxis of renal allograft rejection. Management includes initiation, stabilisation and review of therapy as required

**Authority required (STREAMLINED)**

3356 Management of rejection, under the supervision and direction of a transplant unit, in patients receiving this drug for prophylaxis of cardiac allograft rejection. Management includes initiation, stabilisation and review of therapy as required

**Caution**

Careful monitoring of patients is mandatory.

**Note**

For item codes 9501C and 1839T, pharmaceutical benefits that have the form capsule 250 mg are equivalent for the purposes of substitution.

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<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
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<td>*701.76 a</td>
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**Note**

For item codes 9501C and 1839T, pharmaceutical benefits that have the form capsule 250 mg are equivalent for the purposes of substitution.

**Authority required (STREAMLINED)**

3355 Management of rejection, under the supervision and direction of a transplant unit, in patients receiving this drug for prophylaxis of renal allograft rejection.
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<tr>
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<td>Rapamune PF</td>
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**NATALIZUMAB**

**Authority required (STREAMLINED)**

3425 : Treatment, as monotherapy, by a neurologist, of clinically definite relapsing-remitting multiple sclerosis in an ambulatory (without assistance or support) patient 18 years of age or older, who has experienced at least 2 documented attacks of neurological dysfunction, believed to be due to multiple sclerosis, in the preceding 2 years.

The diagnosis must be confirmed by magnetic resonance imaging of the brain and/or spinal cord and the date of the scan included in the patient's medical notes, unless written certification provided by a radiologist that an MRI scan is contraindicated because of the risk of physical (not psychological) injury to the patient is included in the patient's medical notes.

Natalizumab must be ceased if there is continuing progression of disability while on treatment with natalizumab. For continued treatment the patient must demonstrate compliance with, and an ability to tolerate, natalizumab

**Caution**

Progressive multifocal leukoencephalopathy has been reported with this drug.

**Note**

Neurologists prescribing natalizumab under the PBS listing must be registered with the Tysabri Australian Prescribing Program.

**Note**

Special Pricing Arrangements apply.

<table>
<thead>
<tr>
<th>Code</th>
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<td>9505G</td>
<td>natalizumab 300 mg/15 mL injection, 1 x 15 mL vial</td>
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**SIROLIMUS**

**Authority required (STREAMLINED)**

3355 : Management of rejection, under the supervision and direction of a transplant unit, in patients receiving this drug for prophylaxis of renal allograft rejection. Management includes initiation, stabilisation and review of therapy as required

**Caution**

Careful monitoring of patients is mandatory.

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**Tumor necrosis factor alpha (TNF-) inhibitors**

**ADALIMUMAB**

**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 12 months)

**Clinical criteria:**

Patient must have severe active juvenile idiopathic arthritis,

AND
## HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

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<tr>
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<tbody>
<tr>
<td></td>
<td>Patient must have received no prior PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition; OR</td>
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<td></td>
<td>Patient must not have received PBS-subsidised treatment with adalimumab, etanercept or tocilizumab for this condition in the previous 12 months, AND</td>
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<td></td>
<td>Patient must have demonstrated severe intolerance of, or toxicity due to, methotrexate; OR</td>
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<tr>
<td></td>
<td>Patient must have demonstrated failure to achieve an adequate response to 1 or more of the following treatment regimens: (i) oral or parenteral methotrexate at a dose of at least 20 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; or (ii) oral methotrexate at a dose of at least 10 mg per square metre weekly together with at least 1 other disease modifying anti-rheumatic drug (DMARD), alone or in combination with corticosteroids, for a minimum of 3 months, AND</td>
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<td></td>
<td>Patient must not receive more than 16 weeks of treatment under this restriction. Population criteria: Patient must be under 18 years of age and a parent or authorised guardian must have signed a patient acknowledgement. Treatment criteria: Must be treated by a paediatric rheumatologist; OR</td>
<td></td>
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<tr>
<td></td>
<td>Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre. For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab. Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours. Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis. If treatment with methotrexate alone or in combination with another DMARD is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application. If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application. The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application: (a) an active joint count of at least 20 active (swollen and tender) joints; OR (b) at least 4 active joints from the following list: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). The joint count assessment must be performed preferably whilst still on DMARD treatment, but no longer than 4 weeks following cessation of the most recent prior treatment. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form; and (3) an acknowledgement signed by a parent or authorised guardian. At the time of authority application, medical practitioners must request the appropriate number of injections of appropriate strength, based on the weight of the patient, to provide sufficient for two doses. Up to a maximum of 3 repeats will be authorised. If a patient fails to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle. A patient may re-trial adalimumab after a minimum of 12 months have elapsed between the date the last PBS-subsidised bDMARD was stopped and the date of the first application under a new treatment cycle. Note</td>
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</table>
Note
Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Note
TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient who has severe active juvenile idiopathic arthritis. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.
A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.
From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:
(i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and
(ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.
Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised biological therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.
A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 12 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.
A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 12 months may commence a further course of treatment within the same treatment cycle.
A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake.
(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 12 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 12 months in PBS-subsidised therapy with that agent (Initial 2).
Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.
A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
(b) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 12 months.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.

(4) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 12 months, must requalify for treatment under the Initial 1 treatment restriction.

(5) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with bDMARDs should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to the Department of Human Services at the time treatment is ceased.

**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after break of less than 12 months)

**Clinical criteria:**

Patient must have a documented history of severe active juvenile idiopathic arthritis,

AND

Patient must have received prior PBS-subsidised treatment with adalimumab, etanercept or tocilizumab for this condition in this treatment cycle,

AND

Patient must not have failed PBS-subsidised therapy with adalimumab for this condition in the current treatment cycle,

AND

Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

Patient must be under 18 years of age.

**Treatment criteria:**

Must be treated by a paediatric rheumatologist; OR

Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners must request the appropriate number of injections of appropriate strength, based on the weight of the patient, to provide sufficient for two doses. Up to a maximum of 3 repeats will be authorised.

Applications for a patient who has received PBS-subsidised treatment with adalimumab in this treatment cycle and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient’s most recent course of PBS-subsidised adalimumab treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised adalimumab treatment was approved under either of the Initial 1 or 2 treatment restrictions, the
patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised adalimumab treatment was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with adalimumab.

If a patient fails to respond to PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Note

TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient who has severe active juvenile idiopathic arthritis. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.

From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised biological therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 12 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 12 months may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.

(a) Initial treatment.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy. A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current course of treatment.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 12 months.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.

(4) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 12 months, must requalify for treatment under the Initial 1 treatment restriction.

(5) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with bDMARDS should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to the Department of Human Services at the time treatment is ceased.

**Authority required**

Severe active juvenile idiopathic arthritis

**Treatment Phase:** Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 12 months) or Initial 2 (change or recommencement of treatment after break of less than 12 months) – balance of supply

**Clinical criteria:**

- Patient must have received insufficient adalimumab therapy under the Initial 1 (new patient or patient recommencing treatment after break of more than 12 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient adalimumab therapy under the Initial 2 (change or recommencement of treatment after break of less than 12 months) restriction to complete 16 weeks treatment, AND...
The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Treatment criteria:**

Must be treated by a paediatric rheumatologist; OR

Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

**Note**

Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment

**Clinical criteria:**

Patient must have a documented history of severe active juvenile idiopathic arthritis,

AND

Patient must have demonstrated an adequate response to treatment with adalimumab,

AND

Patient must have received adalimumab as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment in this treatment cycle,

AND

Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

**Treatment criteria:**

Must be treated by a rheumatologist; OR

Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurement of joint count submitted with the initial treatment application.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners must request the appropriate number of injections of appropriate strength, based on the weight of the patient, to provide sufficient for two doses. Up to a maximum of 5 repeats will be authorised.

All applications for continuing treatment with adalimumab must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with adalimumab, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial
Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with adalimumab.

If a patient fails to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle.

**Note**

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

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**Note**

TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient who has severe active juvenile idiopathic arthritis. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.

From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised biological therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 12 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 12 months may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 12 months (Initial 1); or

(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or

(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 12 months in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient
(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 12 months.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have not failed to respond to prior treatment with that drug within the current treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.

(4) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 12 months, must re qualify for treatment under the initial 1 treatment restriction.

(5) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with bDMARDs should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to the Department of Human Services at the time treatment is ceased.

**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment – balance of supply

**Clinical criteria:**

Patient must have received insufficient adalimumab therapy under the Continuing treatment restriction to complete 24 weeks treatment,

AND

The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Treatment criteria:**

Must be treated by a rheumatologist; OR

Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

**Note**

Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:

Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

<table>
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</tbody>
</table>
ETANERCEPT

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have a documented history of severe active juvenile idiopathic arthritis,

AND

Patient must have demonstrated an adequate response to treatment with etanercept,

AND

Patient must have received etanercept as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment in this treatment cycle,

AND

Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a rheumatologist; OR

Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

For the purposes of this restriction ‘biological disease modifying anti-rheumatic drug’ and ‘bDMARD’ mean adalimumab, etanercept or tocilizumab.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurement of joint count submitted with the initial treatment application.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

Where a patient with severe active juvenile idiopathic arthritis continues treatment with etanercept and is 18 years or older, etanercept 50 mg may be prescribed.

At the time of authority application, medical practitioners must request the appropriate number of injections to provide sufficient for four weeks of treatment. Up to a maximum of 5 repeats will be authorised.

All applications for continuing treatment with etanercept must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with etanercept, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with etanercept.

If a patient fails to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle.
Note
Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
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Note
TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient who has severe active juvenile idiopathic arthritis. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMDARPs at any one time.

From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and
(ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised biological therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 12 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 12 months may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 12 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 12 months in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from...
the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 12 months.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.

(4) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.
A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 12 months, must requalify for treatment under the Initial 1 treatment restriction.

(5) Withdrawal of treatment after sustained remission.
Withdrawal of treatment with bDMARDs should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to the Department of Human Services at the time treatment is ceased.

Authority required
Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment – balance of supply

Clinical criteria:
Patient must have received insufficient etanercept therapy under the Continuing treatment restriction to complete 24 weeks treatment,

AND
The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

Treatment criteria:
Must be treated by a rheumatologist; OR
Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Note
Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

5735W ETANERCEPT Injection 50 mg in 1 mL single use auto-injector, 4, 1

5733R ETANERCEPT Injections 50 mg in 1 mL single use pre-filled syringes, 4, 1

ETANERCEPT

Authority required
Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 12 months)

Clinical criteria:
Patient must have severe active juvenile idiopathic arthritis,

AND
PATIENT must have received no prior PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition; OR

PATIENT must not have received PBS-subsidised treatment with adalimumab, etanercept or tocilizumab for this condition in the previous 12 months;

AND

PATIENT must have demonstrated severe intolerance of, or toxicity due to, methotrexate; OR

PATIENT must have demonstrated failure to achieve an adequate response to 1 or more of the following treatment regimens: (i) oral or parenteral methotrexate at a dose of at least 20 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; or (ii) oral methotrexate at a dose of at least 10 mg per square metre weekly together with at least 1 other disease modifying anti-rheumatic drug (DMARD), alone or in combination with corticosteroids, for a minimum of 3 months;

AND

PATIENT must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

PATIENT must be under 18 years of age and a parent or authorised guardian must have signed a patient acknowledgement.

Treatment criteria:

Must be treated by a paediatric rheumatologist; OR

PATIENT must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

For the purposes of this restriction ‘biological disease modifying anti-rheumatic drug’ and ‘bDMARD’ mean adalimumab, etanercept or tocilizumab.

Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.

Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis.

If treatment with methotrexate alone or in combination with another DMARD is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

(a) an active joint count of at least 20 active (swollen and tender) joints; OR

(b) at least 4 active joints from the following list:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count assessment must be performed preferably whilst still on DMARD treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form; and

(3) an acknowledgement signed by a parent or authorised guardian.

At the time of authority application, medical practitioners must request the appropriate number of injections to provide sufficient for four weeks of treatment. Up to a maximum of 3 repeats will be authorised.

If a patient fails to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle. A patient may re-trial etanercept after a minimum of 12 months have elapsed between the date the last PBS-subsidised bDMARD was stopped and the date of the first application under a new treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake. Commence a new treatment cycle.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.

(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1);
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 12 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 12 months in PBS-subsidised therapy with that agent (Initial 2).

Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised biological therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 12 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 12 months may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 12 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 12 months in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 12 months.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.

(4) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 12 months, must requalify for treatment under the Initial 1 treatment restriction.

(5) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with bDMARDs should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to the Department of Human Services at the time treatment is ceased.

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after break of less than 12 months)

Clinical criteria:

Patient must have a documented history of severe active juvenile idiopathic arthritis,

AND

Patient must have received prior PBS-subsidised treatment with adalimumab, etanercept or tocilizumab for this condition in this treatment cycle,

AND

Patient must not have failed PBS-subsidised therapy with etanercept for this condition in the current treatment cycle,

AND

Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

Patient must be under 18 years of age.

Treatment criteria:

Must be treated by a paediatric rheumatologist; OR

Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

For the purposes of this restriction ‘biological disease modifying anti-rheumatic drug’ and ‘bDMARD’ mean adalimumab, etanercept or tocilizumab.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners must request the appropriate number of injections to provide sufficient for four weeks of treatment. Up to a maximum of 3 repeats will be authorised.

Applications for a patient who has received PBS-subsidised treatment with etanercept in this treatment cycle and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient’s most recent course of PBS-subsidised etanercept treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised etanercept treatment was approved under either of the Initial 1 or 2 treatment restrictions, the
<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
<th>Premium $</th>
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<th>Brand Name and Manufacturer</th>
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patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised etanercept treatment was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with etanercept.

If a patient fails to respond to PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Note

TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient who has severe active juvenile idiopathic arthritis. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.

From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised biological therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 12 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 12 months may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake.

1. How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.

(a) Initial treatment.
Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 12 months (Initial 1); or

(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or

(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 12 months in PBS-subsidised therapy with that agent (Initial 2).  

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 12 months.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.

(4) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 12 months, must requalify for treatment under the Initial 1 treatment restriction.

(5) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with bDMARDs should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to the Department of Human Services at the time treatment is ceased.

Authority required

Severe active juvenile idiopathic arthritis

Clinical criteria:

Patient must have received insufficient etanercept therapy under the Initial 1 (new patient or patient recommencing treatment after a break of more than 12 months) restriction to complete 16 weeks treatment; OR

Patient must have received insufficient etanercept therapy under the Initial 2 (change or recommencement of treatment after break of less than 12 months) restriction to complete 16 weeks treatment,
The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Treatment criteria:**
Must be treated by a paediatric rheumatologist; OR
Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

**Note**
Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

**Authority required**
Severe active juvenile idiopathic arthritis

**Clinical criteria:**
Patient must have a documented history of severe active juvenile idiopathic arthritis,

AND

Patient must have demonstrated an adequate response to treatment with etanercept,

AND

Patient must have received etanercept as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment in this treatment cycle,

AND

Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

**Treatment criteria:**
Must be treated by a rheumatologist; OR
Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurement of joint count submitted with the initial treatment application.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners must request the appropriate number of injections to provide sufficient for four weeks of treatment. Up to a maximum of 5 repeats will be authorised.

All applications for continuing treatment with etanercept must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with etanercept, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment...
NOTE

TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient who has severe active juvenile idiopathic arthritis. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.

From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised biological therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 12 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 12 months may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy [Initial 1]; or

(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 12 months [Initial 1]; or

(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent [Initial 2] [further details are under ‘Swapping therapy’ below]; or

(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 12 months in PBS-subsidised therapy with that agent [Initial 2].

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient course.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with etanercept.

If a patient fails to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle.

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001
(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 12 months.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.

(4) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 12 months, must requalify for treatment under the Initial 1 treatment restriction.

(5) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with bDMARDs should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to the Department of Human Services at the time treatment is ceased.

**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment – balance of supply

**Clinical criteria:**

Patient must have received insufficient etanercept therapy under the Continuing treatment restriction to complete 24 weeks treatment,

AND

The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Treatment criteria:**

Must be treated by a rheumatologist; OR

Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

**Note**

Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

etanercept 25 mg injection [4 x 25 mg vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack

1

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815.00

Enbrel

PF

INFLIXIMAB
<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Authority required (STREAMLINED)</th>
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<tr>
<td>4524</td>
<td>Acute severe ulcerative colitis</td>
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**Clinical criteria:**

Patient must have received an infusion of infliximab for the treatment of this condition as a hospital inpatient no more than two weeks prior to the date of the authority application,

**AND**

Patient must be an adult aged 18 years or older, and prior to initiation of infliximab treatment in hospital must have been experiencing six or more bloody stools per day, plus at least one of the following: (i) Temperature greater than 37.8 degrees Celsius; (ii) Pulse rate greater than 90 beats per minute; (iii) Haemoglobin less than 105 g/L; (iv) Erythrocyte sedimentation rate greater than 30 mm/h; OR

Patient must be a child aged 6 to 17 years inclusive, and prior to initiation of infliximab treatment in hospital must have had a Paediatric Ulcerative Colitis Activity Index (PUCAI) greater than or equal to 65, with the diagnosis confirmed by a gastroenterologist, or a consultant physician as specified below,

**AND**

Patient must have failed to achieve an adequate response to at least 72 hours treatment with intravenous corticosteroids prior to initiation of infliximab treatment in hospital.

**Population criteria:**

Patient must be 6 years of age or older.

**Treatment criteria:**

Must be treated by a gastroenterologist; OR

Must be treated by a consultant physician [internal medicine specialising in gastroenterology, or general medicine specialising in gastroenterology].

For adults aged 18 years or older, failure to achieve an adequate response to intravenous corticosteroid treatment is defined by the Oxford criteria where:

(i) If assessed on day 3, patients pass 8 or more stools per day or 3 or more stools per day with a C-reactive protein (CRP) greater than 45 mg/L

(ii) If assessed on day 7, patients pass 3 or more stools per day with visible blood.

For children aged 6 to 17 years, failure to achieve an adequate response to intravenous corticosteroids means a PUCAI score greater than 45 at 72 hours.

At the time of authority application, prescribers should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg.

Before administering infliximab to a child aged 6 to 17 years, the treating clinician must have consulted with a paediatric gastroenterologist or with an institution experienced in performance of paediatric colectomy. The name of the specialist or institution must be included in the patient’s medical records.

Evidence that the patient meets the PBS restriction criteria must be recorded in the patient’s medical records.

**Note**

No increase in the maximum number of repeats may be authorised.

<table>
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<tr>
<th>Code</th>
<th>Name and Manufacturer</th>
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<tbody>
<tr>
<td>10067W</td>
<td>infliximab 100 mg injection, 1 x 100 mg vial</td>
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</table>
Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; or (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); or (iii) limitation of chest expansion relative to normal values for age and gender,

AND

Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months.

Population criteria:
Patient must be an adult.

Treatment criteria:
Must be treated by a rheumatologist.

The application must include details of the NSAIDs trialled, their doses and duration of treatment.

If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used.

If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication.

If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance.

The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application:
(a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; AND
(b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L.

The BASDAI must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. The BASDAI must be no more than 1 month old at the time of initial application.

Both ESR and CRP measures should be provided with the initial treatment application and both must be no more than 1 month old. If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied.

The authority application must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form which must include the following:
(i) a copy of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroilitis; and
(ii) a completed BASDAI Assessment Form; and
(iii) a completed Exercise Program Self Certification Form included in the supporting information form; and
(iv) a signed patient acknowledgment.

The assessment of the patient’s response to the initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted no later than 4 weeks from the cessation of that treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

A maximum of 18 weeks of treatment with this drug will be approved under this criterion.

At the time of authority application, the doctor should request the appropriate number of vials, based on the weight of the patient, to provide for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.

Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) was approved in this cycle and the date of the first application under a new cycle.

Note
Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Department of Human Services website at www.humanservices.gov.au

Note
For details on the appropriate minimum exercise program that will be accepted for the purposes of administering this restriction, please refer to the Department of Human Services website at www.humanservices.gov.au

Authority required
Ankylosing spondylitis
Treatment Phase: Initial 2 (change or recommencement for all patients)

Clinical criteria:
Patient must have a documented history of active ankylosing spondylitis,

AND

Patient must have received prior PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition in this treatment cycle.
From 1 March 2007, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised treatment with only 1 of the 5 bDMARDs at any 1 time.

A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new course of treatment within the same treatment cycle.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once. A patient who received PBS-subsidised bDMARD treatment prior to 1 March 2007 is considered to be in their first cycle as of 1 March 2007. A patient who received PBS-subsidised bDMARD treatment was approved under either of the initial treatment restrictions (i.e. for patients with no prior PBS-subsidised bDMARD therapy or, under this restriction, for patients who have received previous PBS-subsidised bDMARD therapy) the patient must have been assessed for response to that course following a minimum of 12 weeks of treatment. These assessments must be provided to the Department of Human Services no later than 4 weeks from the date the course was ceased. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, patients must have been assessed for response, and the assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and
(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form.

A maximum of 18 weeks of treatment with this drug will be approved under this criterion.

At the time of authority application, the doctor should request the appropriate number of vials, based on the weight of the patient, to provide for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.

Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised bDMARD was approved in this cycle and the date of the first application under a new cycle.

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

TREATMENT OF ADULT PATIENTS WITH ACTIVE ANKYLOSING SPONDYLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, certolizumab pegol, etanercept, golimumab and infliximab for adult patients with active ankylosing spondylitis.

Where the term 'bDMARD' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 5 bDMARDs at any 1 time.

From 1 March 2007, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised bDMARDs without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a bDMARD while they continue to show a response to therapy.

A patient who received PBS-subsidised bDMARD treatment prior to 1 March 2007 is considered to be in their first cycle as of 1 March 2007. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once. A patient who, prior to 1 March 2007, was authorised to receive PBS-subsidised initial treatment for ankylosing spondylitis with the same agent twice, is exempt from this condition in respect of applications approved prior to 1 March 2007.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised bDMARD therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised bDMARD treatment in the most recent cycle to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
(ii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or
(iii) a patient wishes to re-commence treatment with a specific bDMARD following a break in PBS-subsidised therapy with that agent (Initial 2).

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI), or the prior NSAID therapy and exercise program requirements.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements.

For a new patient, the BASDAI used to determine the baseline must be measured while the patient is receiving NSAID therapy and completing their exercise program.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with at least 1 NSAID, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the BASDAI, ESR and/or CRP levels are measured.

**Authority required**

Ankylosing spondylitis

Treatment Phase: Initial treatment – Initial 1 (new patients) or Initial 2 (change or recommencement for all patients) – balance of supply

**Clinical criteria:**

Patient must have active, or a documented history of active, ankylosing spondylitis, AND

Patient must have received insufficient therapy with this drug under the Initial 1 (new patients) restriction to complete 18 weeks treatment; OR

Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement for all patients) restriction to complete 18 weeks treatment, AND
### HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

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<th>Code</th>
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<th>No. of Rpts</th>
<th>Premium $</th>
<th>Dispensed Price for Max. Qty $</th>
<th>Brand Name and Manufacturer</th>
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The treatment must provide no more than the balance of up to 18 weeks treatment available under the above restrictions.

**Population criteria:**
Patient must be an adult.

**Treatment criteria:**
Must be treated by a rheumatologist.

**Note**
Authority approval for sufficient therapy to complete a maximum of 18 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 18 weeks of treatment should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

**Authority required**
Ankylosing spondylitis
Treatment Phase: Continuing treatment

**Clinical criteria:**
Patient must have a documented history of active ankylosing spondylitis,

AND
Patient must have received this drug as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment in this treatment cycle,

AND
Patient must have demonstrated an adequate response to treatment with this drug.

**Population criteria:**
Patient must be an adult.

**Treatment criteria:**
Must be treated by a rheumatologist.

An adequate response is defined as an improvement from baseline of at least 2 of the BASDAI and 1 of the following:
(a) an ESR measurement no greater than 25 mm per hour; or
(b) a CRP measurement no greater than 10 mg per L; or
(c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and supplied in all subsequent continuing treatment applications.

The authority application must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form.

All measurements provided must be no more than 1 month old at the time of application.

A maximum of 24 weeks of treatment with this drug will be authorised under this criterion.

At the time of authority application, the doctor should request the appropriate number of vials, based on the weight of the patient, to provide for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.

All applications for continuing treatment with this drug must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment following an initial treatment course it must be made following a minimum of 12 weeks of treatment with this drug. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised bDMARD was approved in this cycle and the date of the first application under a new cycle.

**Note**
Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
**TREATMENT OF ADULT PATIENTS WITH ACTIVE ANKYLOSING SPONDYLITIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, certolizumab pegol, etanercept, golimumab and infliximab for adult patients with active ankylosing spondylitis.

Where the term 'bDMARD' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 5 bDMARDs at any 1 time.

From 1 March 2007, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised bDMARDs without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a bDMARD while they continue to show a response to therapy.

A patient who received PBS-subsidised bDMARD treatment prior to 1 March 2007 is considered to be in their first cycle as of 1 March 2007. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once. A patient who, prior to 1 March 2007, was authorised to receive PBS-subsidised initial treatment for ankylosing spondylitis with the same agent twice, is exempt from this condition in respect of applications approved prior to 1 March 2007.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised bDMARD therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised bDMARD treatment in the most recent cycle to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

1. How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to re-commence treatment with a specific bDMARD following a break in PBS-subsidised therapy with that agent (Initial 2).

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 2 weeks prior to the Department of Human Services.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI), or the prior NSAID therapy and exercise program requirements.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority
(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements.

For a new patient, the BASDAI used to determine the baseline must be measured while the patient is receiving NSAID therapy and completing their exercise program.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with at least 1 NSAID, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the BASDAI, ESR and/or CRP levels are measured.

**Authority required**

Ankylosing spondylitis

Treatment Phase: Continuing treatment – balance of supply

Clinical criteria:

Patient must have a documented history of active ankylosing spondylitis,

AND

Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment,

AND

The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

Population criteria:

Patient must be an adult.

Treatment criteria:

Must be treated by a rheumatologist.

**Note**

Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

5753T infliximab 100 mg injection, 1 x 100 mg vial 1 .. .. 751.70 Remicade JC

**INFLIXIMAB**

**Authority required**

Initial 1 (new patients)

Initial treatment of Crohn disease in a patient assessed by CDAI.

Initial PBS-subsidised treatment with infliximab by a gastroenterologist or a consultant physician as specified in the NOTE below, of a patient with severe refractory Crohn disease who satisfies the following criteria:

(a) has confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician as specified in the NOTE below; and

(b) has signed a patient acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and

(c) has failed to achieve an adequate response to prior systemic therapy including:

(i) a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period; and

(ii) immunosuppressive therapy including:

— azathioprine at a dose of at least 2 mg per kg daily for 3 or more months; or

— 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months; or

— methotrexate at a dose of at least 15 mg weekly for 3 or more months.
If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of the accepted toxicities including severity can be found on the Medicare Australia website (www.medicareaustralia.gov.au).

The following initiation criterion indicates failure to achieve an adequate response and must be demonstrated in all patients at the time of the application:

(a) have a severity of disease activity which results in a Crohn Disease Activity Index (CDAI) Score greater than or equal to 300 as assessed.

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

The most recent CDAI assessment must be no more than 1 month old at the time of application.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) the completed current Crohn Disease Activity Index (CDAI) calculation sheet including the date of assessment of the patient's condition; and

(ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and

(iii) the signed patient acknowledgement.

A maximum quantity and number of repeats to provide for an initial course of infliximab consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of infliximab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

A CDAI assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment

**Authority required**

**Initial 2**

Change or re-commencement of treatment of Crohn disease in a patient assessed by CDAI.

Initial PBS-subsidised treatment with infliximab by a gastroenterologist or a consultant physician as specified in the NOTE below of a patient who:

(a) has a documented history of severe refractory Crohn disease; and

(b) in this treatment cycle, has received prior PBS-subsidised treatment with infliximab or adalimumab for this condition; and

(c) has not failed PBS-subsidised therapy with infliximab for this condition more than once in the current treatment cycle.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of TNF-alfa antagonist therapy within the timeframes specified in the relevant restriction.

Where the most recent course of PBS-subsidised TNF-alfa antagonist treatment was approved under an initial treatment restriction, the patient must have been assessed for response to that course following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

If the response assessment to the previous course of TNF-alfa antagonist treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of TNF-alfa antagonist.

Authority applications must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) the completed current Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of assessment of the patient's condition; and

(ii) details of prior TNF alfa antagonist treatment including details of date and duration of treatment.

A maximum quantity and number of repeats to provide for an initial course of infliximab consisting of 3 doses at 5 mg per kg body weight per dose to
be administered at weeks 0, 2 and 6, will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of infliximab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

A CDAI assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment.

**Authority required**

Continuing treatment of Crohn disease in a patient assessed by CDAI.

Continuing PBS-subsidised treatment with infliximab by a gastroenterologist, a consultant physician as specified in the NOTE below or other consultant physician in consultation with a gastroenterologist, of a patient who:

(a) has a documented history of severe refractory Crohn disease; and

(b) has demonstrated or sustained an adequate response to treatment with infliximab.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

An adequate response to infliximab treatment is defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) the completed Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient’s condition.

The CDAI assessment must be no more than 1 month old at the time of application.

If the application is the first application for continuing treatment with infliximab, a CDAI assessment of the patient’s response must be made up to 12 weeks after the first dose so that there is adequate time for a response to be demonstrated.

The assessment of the patient’s response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with infliximab.

Patients are eligible to receive continuing infliximab treatment in courses of up to 24 weeks providing they continue to sustain the response.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised. No applications for increased repeats will be authorised.

Where fewer than 2 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Authority required**

Initial 1

Initial treatment of Crohn disease in a patient with short gut syndrome or an ostomy patient.

Initial PBS-subsidised treatment with infliximab by a gastroenterologist, or consultant physician as specified in the NOTE below of a patient who meets the following criteria:

(a) has confirmed Crohn disease defined by standard clinical, endoscopic and/or imaging features, including histological evidence with the diagnosis confirmed by a gastroenterologist or consultant physician as specified in the NOTE below; and

(b) has diagnostic imaging or surgical evidence of short gut syndrome or has an ileostomy or colostomy; and

(c) has evidence of intestinal inflammation; and

(d) has signed a patient acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and

(e) has failed to achieve an adequate response to prior systemic drug therapy including:

(i) a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period; and

(ii) immunosuppressive therapy including:

— azathioprine at a dose of at least 2 mg per kg daily for 3 or more months; or

— 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months; or
NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of the accepted toxicities including severity can be found on the Medicare Australia website (www.medicareaustralia.gov.au).

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the application:

(a) have evidence of intestinal inflammation, including:

(i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; AND/OR

(ii) faeces: higher than normal lactoferrin or calprotectin level; AND/OR

(iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery;

AND/OR

(b) be assessed clinically as being in a high faecal output state;

AND/OR

(c) be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of infliximab.

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the continuing treatment restriction. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and

(ii) reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; and

(iii) date of the most recent clinical assessment; and

(iv) the signed patient acknowledgement.

All assessments, pathology tests and diagnostic imaging studies must be made within 1 month of the date of application.

A maximum quantity and number of repeats to provide for an initial course of infliximab consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of infliximab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

The assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment

**Authority required**

**Initial 2**

Change or re-commencement of treatment of Crohn disease in a patient with short gut syndrome, an ostomy patient or a patient with extensive small intestine disease.

Initial PBS-subsidised treatment with infliximab by a gastroenterologist or a consultant physician as specified in the NOTE below of a patient who:

(a) has a documented history of severe refractory Crohn disease; and

(b) in this treatment cycle, has received prior PBS-subsidised treatment with infliximab or adalimumab for this condition; and

(c) has not failed PBS-subsidised therapy with infliximab for this condition more than once in the current treatment cycle.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].
To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of TNF-alfa antagonist therapy within the timeframes specified in the relevant restriction.

Where the most recent course of PBS-subsidised TNF-alfa antagonist treatment was approved under an initial treatment restriction, the patient must have been assessed for response to that course following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

If the response assessment to the previous course of TNF-alfa antagonist treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of TNF-alfa antagonist.

Authority applications must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criteria, if relevant; and

(ii). details of prior TNF alfa antagonist treatment including details of date and duration of treatment.

A maximum quantity and number of repeats to provide for an initial course of infliximab consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

The assessment of the patient’s response to this initial course of treatment must be made following a minimum of 12 weeks of therapy so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment.

**Authority required**

Continuing treatment of Crohn disease in a patient with short gut syndrome or an ostomy patient.

Continuing PBS-subsidised treatment with infliximab by a gastroenterologist, a consultant physician as specified in the NOTE below or other consultant physician in consultation with a gastroenterologist, of a patient who:

(a) has a documented history of severe refractory Crohn disease with intestinal inflammation and with short gut syndrome or with an ileostomy or colostomy; and

(b) has demonstrated or sustained an adequate response to treatment with infliximab.

**NOTE:** Prescribers must be gastroenterologists [code 87], consultant physicians [internal medicine specialising in gastroenterology [code 81]] or consultant physicians [general medicine specialising in gastroenterology [code 82]].

An adequate response to infliximab treatment is defined as:

(a) improvement of intestinal inflammation as demonstrated by:

(i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; AND/OR

(ii) faeces: normalisation of lactoferrin or calprotectin level; AND/OR

(iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or

(b) reversal of high faecal output state; or

(c) avoidance of the need for surgery or total parenteral nutrition (TPN).

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) the reports and dates of the pathology or diagnostic imaging test(s) used to assess response to therapy or the date of clinical assessment.

The patient’s assessment must be no more than 1 month old at the time of application.

If the application is the first application for continuing treatment with infliximab, an assessment of the patient’s response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

The assessment of the patient’s response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled. In order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with infliximab.
Patients are eligible to receive continuing infliximab treatment in courses of up to 24 weeks providing they continue to sustain the response.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised. No applications for increased repeats will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday)

**Authority required**

**Initial 1**

Initial treatment of Crohn disease in a patient with extensive small intestine disease.

Initial PBS-subsidised treatment with infliximab by a gastroenterologist or a consultant physician as specified in the NOTE below, of a patient with severe refractory Crohn disease who satisfies the following criteria:

(a) has confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or consultant physician as specified in the NOTE below; and

(b) has extensive small intestinal disease with radiological evidence of intestinal inflammation affecting more than 50 cm of the small intestine; and

(c) has signed a patient acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and

(d) has failed to achieve an adequate response to prior systemic therapy including:

(i) a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period; and

(ii) immunosuppressive therapy including:

—— azathioprine at a dose of at least 2 mg per kg daily for 3 or more months; or

—— 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months; or

—— methotrexate at a dose of at least 15 mg weekly for 3 or more months.

**NOTE:** Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of the accepted toxicities including severity can be found on the Medicare Australia website ([www.medicareaustralia.gov.au](http://www.medicareaustralia.gov.au)).

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the application:

(a) have severity of disease activity which results in a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220;

AND/OR

(b) have evidence of active intestinal inflammation, including:

(i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; AND/OR

(ii) faeces: higher than normal lactoferrin or calprotectin level; AND/OR

(iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery;

AND/OR

(c) be assessed clinically as being in a high faecal output state;

AND/OR

(d) be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of infliximab.

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the continuing treatment restriction. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website ([www.medicareaustralia.gov.au](http://www.medicareaustralia.gov.au))] which includes the following:

(i) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and

(ii) (1) reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; or

(ii) (2) the completed current Crohn Disease Activity Index (CDAI) calculation sheet including the dates of assessment of the patient's condition, if
Monday to Friday weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

The assessment of the patient’s response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment.

**Authority required**

Continuing treatment of Crohn disease in a patient with extensive small intestine disease.

Continuing PBS-subsidised treatment with infliximab by a gastroenterologist, or consultant physician as specified in the NOTE below or other consultant physician in consultation with a gastroenterologist, of a patient who:

(a) has a documented history of severe refractory Crohn disease with extensive intestinal inflammation affecting more than 50 cm of the small intestine; and

(b) has demonstrated or sustained an adequate response to treatment with infliximab.

**NOTE:** Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

An adequate response to infliximab treatment is defined as:

(a) a reduction in Crohn Disease Activity Index (CDAI) Score to no greater than 150; or

(b) improvement of intestinal inflammation as demonstrated by:

(i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; AND/OR

(ii) faeces: normalisation of lactoferrin or calprotectin level; AND/OR

(iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or

(c) reversal of high faecal output state; or

(d) avoidance of the need for surgery or total parenteral nutrition (TPN).

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) the completed Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient’s condition; or

(ii) the reports and dates of the pathology test or diagnostic imaging test(s) used to assess response to therapy; or

(iii) the date of clinical assessment.

All assessments must be no more than 1 month old at the time of application.

If the application is the first application for continuing treatment with infliximab, an assessment of the patient’s response must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

The assessment of the patient’s response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment.

**Supporting Information Form**

Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) the completed Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient’s condition; or

(ii) the reports and dates of the pathology test or diagnostic imaging test(s) used to assess response to therapy; or

(iii) the date of clinical assessment.

All assessments must be no more than 1 month old at the time of application.

If the application is the first application for continuing treatment with infliximab, an assessment of the patient’s response must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

The assessment of the patient’s response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with infliximab.

Patients are eligible to receive continuing infliximab treatment in courses of up to 24 weeks providing they continue to sustain the response.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised. No applications for increased repeats will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday)
NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultan physicians [general medicine specialising in gastroenterology (code 82)].

An adequate response to infliximab treatment is defined as a reduction in Crohn Disease Activity Index (CDAI) Score to no greater than 150.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) the completed current and baseline Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient’s condition; and

(ii) the signed patient acknowledgement.

The current CDAI assessment must be no more than 1 month old at the time of application. The baseline CDAI assessment must be from immediately prior to commencing treatment with infliximab.

The assessment of the patient’s response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with infliximab.

Patients are eligible to receive continuing infliximab treatment in courses of up to 24 weeks providing they continue to sustain the response.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised. No applications for increased repeats will be authorised.

Where fewer than 2 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Patients may qualify for PBS-subsidised treatment under this restriction only once Authority required

Initial PBS-subsidised treatment of Crohn disease in a patient with short gut syndrome, an ostomy patient, or a patient with extensive small intestine disease, who has previously received non-PBS-subsidised therapy with infliximab.

Initial PBS-subsidised supply for continuing treatment with infliximab by a gastroenterologist, a consultant physician as specified in the NOTE below, or other consultant physician in consultation with a gastroenterologist of a patient who:

(a) has a documented history of severe refractory Crohn disease and was receiving treatment with infliximab prior to 7 March 2007; and

(b) had a Crohn Disease Activity Index (CDAI) Score of greater than or equal to 300 prior to commencing treatment with infliximab. Where a baseline CDAI assessment is not available, please call Medicare Australia on 1800 700 270 to discuss; and

(c) has signed a patient acknowledgement indicating that they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and

(d) has demonstrated or sustained an adequate response to treatment with infliximab. For advice please contact Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

The same criteria used to determine an inadequate response to prior treatment at baseline must be used to determine response to treatment and eligibility for continuing therapy, according to the criteria included in the continuing treatment restriction.

An adequate response to infliximab treatment is defined as:
Any queries concerning the arrangements to prescribe infliximab may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authority to prescribe infliximab should be forwarded to:
Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

**Note**

TREATMENT OF ADULT PATIENTS WITH SEVERE REFRACTORY CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab and infliximab for adult patients with severe refractory Crohn disease. Where the term ‘tumour necrosis factor (TNF) alfa antagonist’ appears in the following NOTES and restrictions, it refers to adalimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 2 TNF-alfa antagonists at any 1 time.

From 1 August 2008, under the PBS, all patients will be able to commence a treatment cycle where they may trial each PBS-subsidised TNF-alfa antagonist without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a TNF-alfa antagonist while they continue to show a response to therapy.

A patient who received PBS-subsidised TNF-alfa antagonist treatment prior to 1 August 2008 is considered to be in their first cycle as of 1 August 2008.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised TNF-alfa antagonist more than twice.
Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised TNF-alfa antagonist therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised TNF-alfa antagonist treatment in the most recent cycle to the date of the first application for initial treatment with a TNF-alfa antagonist under the new treatment cycle.

A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised TNF-alfa antagonist therapy after 1 August 2008.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised TNF-alfa antagonist treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) TNF-alfa antagonist therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or

(iii) a patient wishes to re-commence treatment with a specific TNF-alfa antagonist following a break in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks of therapy for infliximab.

From 1 August 2008, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

For second and subsequent courses of PBS-subsidised TNF-alfa antagonist treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Adalimumab only: Two completed authority prescriptions must be submitted with every initial application for adalimumab. One prescription must be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats. The second prescription must be written for 2 doses of 40 mg and 2 repeats.

(b) Continuing treatment. Following the completion of an initial treatment course with a specific TNF-alfa antagonist, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing TNF-alfa antagonist treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted TNF-alfa antagonist supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised TNF-alfa antagonist is approved, a patient may swap if eligible to the alternate TNF-alfa antagonist within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Crohn Disease Activity Index (CDAI) Score, evidence of intestinal inflammation), or the prior corticosteroid therapy and immunosuppressive therapy.

A patient may trial the alternate TNF-alfa antagonist at any time, regardless of whether they are receiving therapy (initial or continuing) with a TNF-alfa antagonist at the time of the application. However, they cannot swap to a particular TNF-alfa antagonist if they have failed to respond to prior treatment with that drug two times within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to the alternate TNF-alfa antagonist should be accompanied by the approved authority prescription or remaining repeats for the TNF-alfa antagonist the patient is ceasing.

(3) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the CDAI or evidence of intestinal inflammation submitted with the first authority application for a TNF-alfa antagonist. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and Medicare Australia will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised TNF-alfa antagonist therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with a corticosteroid and at least 1 immunosuppressive agent, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the CDAI score or the indices of intestinal inflammation are measured.

(5) Patients 'grandfathered' onto PBS-subsidised treatment with adalimumab or infliximab.

A patient who commenced treatment with adalimumab for severe refractory Crohn disease prior to 9 November 2007 or infliximab prior to 7 March 2007 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 'grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with adalimumab or infliximab will be authorised under this criterion.

Following completion of the initial PBS-subsidised course, further applications for treatment with adalimumab or infliximab will be assessed under the continuing treatment restriction.

'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must requalify for initial treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' above for further details.

### INFLIXIMAB

**Authority required**

Initial treatment of Crohn disease in a paediatric patient.

Initial PBS-subsidised treatment by a gastroenterologist, paediatrician or consultant physician as specified in the NOTE below, of a patient aged 6 to 17 years inclusive with moderate to severe refractory Crohn disease who satisfies the following criteria:

(a) has confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or consultant physician as specified in the NOTE below; and

(b) whose parent or authorised guardian has signed a patient acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and

(c) has failed to achieve an adequate response to 2 of the following 3 conventional prior therapies including:

(i) a tapered course of steroids, starting at a dose of at least 1 mg per kg or 40 mg (whichever is the lesser) prednisolone (or equivalent), over a 6 week period;

(ii) an 8 week course of enteral nutrition;

(iii) immunosuppressive therapy including:

— azathioprine at a dose of at least 2 mg per kg daily for 3 or more months; or

— 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months; or

— methotrexate at a dose of at least 10 mg per square metre weekly for 3 or more months.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of the accepted toxicities including severity can be found on the Medicare Australia website (www.medicareaustralia.gov.au).

The following initiation criterion indicates failure to achieve an adequate response and must be demonstrated in all patients at the time of the application:

(a) severity of disease activity which results in a Paediatric Crohn Disease Activity Index (PCDAI) Score greater than or equal to 30 as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

(b) The most recent PCDAI assessment must be no more than 1 month old at the time of application.

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) the completed current Paediatric Crohn Disease Activity Index (PCDAI) calculation sheet including the date of assessment of the patient’s condition; and

(ii) details of previous systemic drug therapy [dosage, date of commencement and duration of therapy], or dates of enteral nutrition; and

(iii) the signed patient acknowledgement.

A maximum quantity and number of repeats to provide for an initial course of infliximab consisting of 3 doses at 5 mg per kg body weight per dose

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Patients are eligible to receive continuing infliximab treatment in courses of up to 24 weeks providing they continue to sustain the response. Patients who fail to demonstrate or sustain a response to treatment with infliximab for Crohn disease as specified in the criteria for continuing and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to those patients who meet the continuation criterion.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment

**Authority required**

Continuing treatment of Crohn disease in a patient initiated on PBS-subsidised treatment as a paediatric patient.

Continuing PBS-subsidised treatment with infliximab by a gastroenterologist, paediatrician, consultant physician as specified in the NOTE below or other consultant physician in consultation with a gastroenterologist, of a patient who:

(a) has a documented history of moderate to severe refractory Crohn disease; and

(b) has demonstrated or sustained an adequate response to treatment with infliximab.

**NOTE:** Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

An adequate response to infliximab treatment is defined as a reduction in Paediatric Crohn Disease Activity Index (PCDAI) Score by at least 15 points as compared to baseline AND a total PCDAI score of 30 points or less.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Crohn disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) the completed Paediatric Crohn Disease Activity Index (PCDAI) calculation sheet along with the date of the assessment of the patient’s condition.

The PCDAI assessment must be no more than 1 month old at the time of application.

If the application is the first application for continuing treatment with infliximab, a PCDAI assessment of the patient’s response must be made up to 12 weeks after the first dose so that there is adequate time for a response to be demonstrated.

The assessment of the patient’s response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with infliximab.

Patients are eligible to receive continuing infliximab treatment in courses of up to 24 weeks providing they continue to sustain the response.

Patients who fail to demonstrate or sustain a response to treatment with infliximab for Crohn disease as specified in the criteria for continuing treatment with infliximab, will not be eligible to receive PBS-subsidised treatment with this drug within 12 months of the date on which treatment was ceased.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised. No applications for increased repeats will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday)

**Authority required**

Initial PBS-subsidised treatment of Crohn disease in a paediatric patient who has previously received non-PBS-subsidised therapy with infliximab.

Initial PBS-subsidised supply for continuing treatment with infliximab by a gastroenterologist, paediatrician, consultant physician as specified in the NOTE below or other consultant physician in consultation with a gastroenterologist, of a patient aged 6 to 17 years inclusive who:

(a) has a documented history of moderate to severe refractory Crohn disease and was receiving treatment with infliximab prior to 4 July 2007; and

(b) had a Paediatric Crohn Disease Activity Index (PCDAI) Score of greater than 30 prior to commencing treatment with infliximab. Where a baseline CDACI assessment is not available, please call Medicare Australia on 1800 700 270 to discuss; and

(c) whose parent or authorised guardian has signed a patient acknowledgement indicating that they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and

(d) has demonstrated or sustained an adequate response to treatment with infliximab. For advice please contact Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**NOTE:** Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].
An adequate response to infliximab treatment is defined as a reduction in Paediatric Crohn Disease Activity Index (PCDAI) Score by at least 15 points as compared to baseline AND a total PCDAI score of 30 points or less.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) the completed current and baseline Paediatric Crohn Disease Activity Index (PCDAI) calculation sheet along with the date of the assessment of the patient’s condition; and

(ii) the signed patient acknowledgement.

The current PCDAI assessment must be no more than 1 month old at the time of application. The baseline PCDAI assessment must be from immediately prior to commencing treatment with infliximab.

The assessment of the patient’s response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with infliximab.

Patients are eligible to receive continuing infliximab treatment in courses of up to 24 weeks providing they continue to sustain the response.

Patients who fail to demonstrate or sustain a response to treatment with infliximab for Crohn disease as specified in the criteria for continuing treatment with infliximab, will not be eligible to recommence PBS-subsidised treatment with this drug within 12 months of the date on which treatment was ceased.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised. No applications for increased repeats will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Patients may qualify for PBS-subsidised treatment under this restriction once only

Note

Any queries concerning the arrangements to prescribe infliximab may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe infliximab should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

5755X
infliximab 100 mg injection, 1 x 100 mg vial

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an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

(i) an active joint count of at least 20 active (swollen and tender) joints; or

(ii) at least 4 active joints from the following list of major joints:

— elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

— shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and

(3) a signed patient acknowledgement.

A maximum of 22 weeks treatment will be authorised under this restriction.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats may be authorised.

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 22 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

The assessment of the patient’s response to the initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Patients who fail to demonstrate a response to treatment with infliximab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug, in this Treatment Cycle. Patients may re-trial infliximab after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

**Authority required**

**Initial 2**

Initial PBS-subsidised treatment with infliximab, by a rheumatologist or clinical immunologist with expertise in the management of psoriatic arthritis, of adults who:

(1) have a documented history of severe active psoriatic arthritis; and

(2) have received prior PBS-subsidised biological treatment for this condition in this Treatment Cycle and are eligible to receive further biological therapy; and

(3) have not failed treatment with infliximab during the current Treatment Cycle.

Applications for patients who have received PBS-subsidised treatment with infliximab within this Treatment Cycle and who wish to re-commence therapy with this drug within this same Cycle, must be accompanied by evidence of a response to the patient’s most recent course of PBS-subsidised infliximab treatment, within the timeframes specified below.

A maximum of 22 weeks treatment will be authorised under this restriction.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats may be authorised.

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 22 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Where the most recent course of PBS-subsidised infliximab treatment was approved under either of the initial treatment restrictions (i.e. for patients with no prior PBS-subsidised biological therapy or, under this restriction, for patients who have received previous PBS-subsidised biological therapy), patients must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be provided to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised infliximab treatment was approved under the continuing treatment criteria, patients must have been assessed for response, and the assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

Patients who fail to demonstrate a response to treatment with infliximab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug, in this Treatment Cycle. Patients may re-trial infliximab after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.
TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents (adalimumab, etanercept, golimumab and infliximab) for adult patients with severe active psoriatic arthritis.

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological agents at any 1 time. Where the term 'biological agents' appears in the following NOTES and restrictions, it only refers to adalimumab, etanercept, golimumab and infliximab.

From 1 August 2006, all patients will be able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

Following demonstration of response to initial treatment, these biological agents are available under the PBS for continuing treatment as set out in the continuing treatment restriction for each agent.

Once patients have either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological therapy before they are eligible to commence another Cycle [further details are under '(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' below].

The 5-year break in therapy will be measured from the date the last approval for PBS-subsidised treatment was granted in the most recent Cycle to the continuing treatment restriction for each agent.

All applications for continuing treatment with infliximab must include a measurement of response to the prior course of therapy. This assessment must have, at a minimum, a 5-year break in PBS-subsidised biological therapy before they are eligible to commence another Cycle [further details are under '(5)  Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' below].
Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular treatment cycle, as defined in the relevant restriction, may commence a further course of treatment within that cycle.

How to prescribe biological agents for the treatment of severe active psoriatic arthritis after 1 August 2010.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); and

(ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; and

(iii) patients wish to re-commence treatment with a specific biological agent following a break in PBS-subsidised therapy with that specific agent (Initial 3).

All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of therapy for all agents except for infliximab, for which a maximum of 22 weeks will be authorised. It is recommended that patients be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological agent supply.

Patients must be assessed for response to any course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

Grandfather patients — golimumab only.

Applications for patients who commenced treatment with golimumab prior to 1 March 2010 may apply for initial PBS-subsidised treatment as continuing therapy under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with any biological agent prior to PBS listing of that agent.

Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment for all agents.

Approval will be based on the criteria included in the relevant restriction.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological agent, patients may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. Patients are eligible to receive continuing biological treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

Patients must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

(3) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate biological agent without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements.

Patients may swap to an alternate biological agent at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological agent at the time of the application or not.

Patients may alternate between therapy with any biological agent of their choice (1 at a time) providing:

(i) they have not received PBS-subsidised treatment with that particular biological agent previously; or

(ii) they have demonstrated an adequate response to that particular biological agent if they have previously trialled it on the PBS; or

(iii) they have not previously failed to respond to treatment 3 times in this Treatment Cycle.

To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the biological agent the patient is ceasing.

(4) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the indices of disease severity submitted with the first authority application for a biological agent. However, prescribers may provide baseline measurements any time that an initial treatment authority is submitted within a treatment cycle and Medicare Australia will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint...
count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

Patients who wish to trial a second or subsequent treatment Cycle following a break in PBS-subsidised biological therapy of at least 5 years, must re-qualify for initial treatment with respect to both the indices of disease severity. Patients must have received treatment with methotrexate and sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured.

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### INFLIXIMAB

#### Authority required

Initial 1 (new patient or patient re-commencing after a break of more than 24 months)

Initial PBS-subsidised treatment with infliximab, in combination with methotrexate at a dose of at least 7.5 mg weekly, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults who:

(a) have severe active rheumatoid arthritis; and

(b) have received no PBS-subsidised treatment with a bDMARD for this condition in the previous 24 months; and

(c) have failed, in the 24 months immediately prior to the date of application, to achieve an adequate response to at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs), which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be:

— hydroxychloroquine at a dose of at least 200 mg daily; or

— leflunomide at a dose of at least 10 mg daily; or

— sulfasalazine at a dose of at least 2 g daily.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, then the 6 months of intensive DMARD treatment must include at least 3 months continuous treatment with each of at least 2 of the DMARDs:

— hydroxychloroquine at a dose of at least 200 mg daily; and/or

— leflunomide at a dose of at least 10 mg daily; and/or

— sulfasalazine at a dose of at least 2 g daily.

The application must include details of the contraindication or intolerance to methotrexate. Details of the toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose can be found on the Medicare Australia website [www.medicareaustralia.gov.au]. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

If 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved product information or cannot be tolerated at the doses specified above, then one or more of the following DMARDs may be used in place of these agents in order to satisfy the requirement for a trial of 6 months of intensive DMARD therapy with at least 2 DMARDs taken continuously for at least 3 months each:

— azathioprine at a dose of at least 1 mg/kg per day; and/or

— cyclosporin at a dose of at least 2 mg/kg/day; and/or

— sodium aurothiomalate at a dose of 50 mg weekly.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances. Details of the toxicities, including severity, which will be accepted as a reason for substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial can be found on the Medicare Australia website [www.medicareaustralia.gov.au].

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance and dose for each DMARD must be provided in the authority application. Details of the toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy can be found on the Medicare Australia website [www.medicareaustralia.gov.au].

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

- an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either
  - (i) a total active joint count of at least 20 active (swollen and tender) joints; or
  - (ii) at least 4 active joints from the following list of major joints:
    - elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
    - shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).
At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 3 mg per kg. Up to a maximum of 3 repeats may be authorised. Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 22 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Assessment of a patient’s response to an initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

Patients who fail to demonstrate a response to treatment with infliximab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition

**Authority required**

Initial 2 (change or re-commencement after break of less than 24 months)

Initial course of PBS-subsidised treatment with infliximab, in combination with methotrexate at a dose of at least 7.5 mg weekly, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults who:

(a) have a documented history of severe active rheumatoid arthritis; and

(b) have received prior PBS-subsidised bDMARD treatment for this condition and are eligible to receive further bDMARD therapy.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and

(3) a signed patient acknowledgement.

A maximum of 22 weeks of treatment will be authorised under this restriction.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 3 mg per kg. Up to a maximum of 3 repeats may be authorised. Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 22 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Assessment of a patient’s response to an initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

Patients who fail to demonstrate a response to treatment with infliximab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition

**Authority required**

Continuing treatment

Continuing PBS-subsidised treatment with infliximab, in combination with methotrexate at a dose of at least 7.5 mg weekly, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults:

(a) who have a documented history of severe active rheumatoid arthritis; and

(b) who have demonstrated an adequate response to treatment with infliximab; and

(c) whose most recent course of PBS-subsidised bDMARD treatment was with infliximab.
A patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and AND either of the following:

(i) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(ii) a reduction in the number of the following major active joints, from at least 4, by at least 50%:
— elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
— shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

A maximum of 24 weeks of treatment will be approved under this restriction.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 3 mg per kg. Up to a maximum of 2 repeats may be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

All applications for continuing treatment with infliximab must include a measurement of response to the prior course of therapy. This assessment is performed on the weight of the patient,

Where a patient cannot tolerate 7.5 mg of methotrexate weekly, they are eligible to receive PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab) and the T-cell co-stimulation modulator (abatacept).

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 weeks...
The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or

(ii) a patient wishes to re-commence treatment with a bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2); or

(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or

(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab and tocilizumab, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to Medicare Australia within 4 weeks.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:

Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient’s weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:

A further application may be submitted to Medicare Australia 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept patients:

Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the
In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

**Note**

(3) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and Medicare Australia will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

**Note**

Special Pricing Arrangements apply.

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**INFliximab**

**Authority required**

Initial treatment [Initial 1, Whole body (New patients — No prior biological agent)]

Initial treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over who:

(i) have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis; and

(ii) have not received any prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle; and

(iii) have signed a patient and prescriber acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment (whole body); and

(iv) have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 3 of the following 4 treatments:

(i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or

(ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; and/or

(iii) cyclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; and/or

(iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity to necessitate permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of acceptable toxicities including severity, associated with phototherapy, methotrexate, cyclosporin and acitretin, can be found on the Medicare Australia website (www.medicareaustralia.gov.au).

The following initiation criterion indicates failure to achieve an adequate response and must be demonstrated in all patients at the time of the application:

(a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 1 month old at the time of application.
Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient’s condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; and

(iii) the signed patient and prescriber acknowledgements.

A maximum of 22 weeks of treatment with infliximab will be authorised under this restriction.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 22 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period beyond 22 weeks.

A PASI assessment of the patient’s response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment

**Authority required**

Initial or re-Treatment [Initial 2. Whole body (Received prior biological agent under PBS)]

Treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over who:

(a) have a documented history of severe chronic plaque psoriasis; and

(b) have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle; and

(c) have not failed PBS-subsidised therapy with infliximab for the treatment of this condition in the current Treatment Cycle.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient’s condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and

(ii) details of prior biological treatment, including dosage, date and duration of treatment.

Applications for patients who have demonstrated a response to PBS-subsidised infliximab treatment within this Treatment Cycle and who wish to re-commence infliximab treatment within the same Cycle following a break in therapy, will only be approved where evidence of the patient’s response to their most recent course of PBS-subsidised infliximab treatment has been submitted to Medicare Australia within 1 month of cessation of treatment.

A maximum of 22 weeks of treatment with infliximab will be authorised under this restriction.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 22 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period beyond 22 weeks.

A PASI assessment of the patient’s response to this course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment

**Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may re-commence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle**
Applications for authorisation must be made in writing and must include:

- Initial course to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised.
- Cycle submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.
- If the patient will be deemed to have failed to respond to treatment with infliximab. In circumstances where it is not possible to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for continuing authority applications, or for treatment that would otherwise extend the treatment period beyond 24 weeks.

A maximum of 24 weeks of treatment with infliximab will be authorised under this restriction.

Approval will be based on the PASI assessment of response to the most recent course of treatment with infliximab.

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the pre-biological treatment baseline value for this Treatment Cycle.

This assessment must be provided to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with infliximab, the assessment of response must be after a minimum of 12 weeks of treatment with an initial course.

Applications for authorisation must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
  - (i) the completed Psoriasis Area and Severity Index (PASI) calculation sheet along with the date of the assessment of the patient’s condition.

The most recent PASI assessment must be no more than 1 month old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with infliximab.

Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may re-commence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

**Authority required**

**Initial treatment** [Initial 1, Face, hand, foot (New patients — No prior biological agent)]

Initial treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over who:

- (a) have a documented history of severe chronic plaque psoriasis; and
- (b) whose most recent course of PBS-subsidised biological treatment for this condition in this Treatment Cycle was with infliximab; and
- (c) who have demonstrated an adequate response to their most recent course of treatment with infliximab.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the pre-biological treatment baseline value for this Treatment Cycle.

If intolerance to treatment develops during the relevant period of use, which is of a severity to necessitate permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of acceptable toxicities including severity, associated with phototherapy, methotrexate, cyclosporin and acitretin, can be found on the Medicare Australia website (www.medicareaustralia.gov.au).

The following initiation criterion indicates failure to achieve an adequate response and must be demonstrated in all patients at the time of the application:

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>Qty $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td></td>
<td>Continuing treatment (Whole body)</td>
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<td>Continuing PBS-subsidised treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over who:</td>
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<td></td>
<td>(a) have a documented history of severe chronic plaque psoriasis; and</td>
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<td>(b) whose most recent course of PBS-subsidised biological treatment for this condition in this Treatment Cycle was with infliximab; and</td>
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<td>(c) who have demonstrated an adequate response to their most recent course of treatment with infliximab.</td>
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<td>An adequate response to treatment is defined as:</td>
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<td>A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the pre-biological treatment baseline value for this Treatment Cycle.</td>
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<td>This assessment must be provided to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with infliximab, the assessment of response must be after a minimum of 12 weeks of treatment with an initial course.</td>
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<td>Applications for authorisation must be made in writing and must include:</td>
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<td>(a) a completed authority prescription form; and</td>
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<td>(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (<a href="http://www.medicareaustralia.gov.au">www.medicareaustralia.gov.au</a>)] which includes the following:</td>
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<td>(i) the completed Psoriasis Area and Severity Index (PASI) calculation sheet along with the date of the assessment of the patient’s condition.</td>
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<td>The most recent PASI assessment must be no more than 1 month old at the time of application.</td>
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<td>Approval will be based on the PASI assessment of response to the most recent course of treatment with infliximab.</td>
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<td>A maximum of 24 weeks of treatment with infliximab will be authorised under this restriction.</td>
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<td>At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised.</td>
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<td>Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for continuing authority applications, or for treatment that would otherwise extend the treatment period beyond 24 weeks.</td>
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<td>A PASI assessment of the patient’s response must be conducted within 4 weeks prior to completion of this course of treatment. This assessment, which will be used to determine eligibility for further continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.</td>
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<td>It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment.</td>
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<td>Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may re-commence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.</td>
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<td><strong>Authority required</strong></td>
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<td>Initial treatment [Initial 1, Face, hand, foot (New patients — No prior biological agent)]</td>
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<td></td>
<td>Initial treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over who:</td>
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<td>(a) have severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis; and</td>
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<td>(b) have not received any prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle; and</td>
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<td>(c) have signed a patient and prescriber acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment (face, hand, foot); and</td>
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<td>(d) have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 3 of the following 4 treatments:</td>
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<td>(i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or</td>
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<td>(ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; and/or</td>
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<td>(iii) cyclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; and/or</td>
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<td>(iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks.</td>
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<td>If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, please provide details at the time of application.</td>
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<td>If intolerance to treatment develops during the relevant period of use, which is of a severity to necessitate permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of acceptable toxicities including severity, associated with phototherapy, methotrexate, cyclosporin and acitretin, can be found on the Medicare Australia website (<a href="http://www.medicareaustralia.gov.au">www.medicareaustralia.gov.au</a>).</td>
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<td>The following initiation criterion indicates failure to achieve an adequate response and must be demonstrated in all patients at the time of the application:</td>
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(a) Chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:

(i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment; or

(ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 1 month old at the time of application.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient’s condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and

(ii) details of prior phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; and

(iii) the signed patient and prescriber acknowledgements.

A maximum of 22 weeks of treatment with infliximab will be authorised under this restriction.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 22 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period beyond 22 weeks.

A PASI assessment of the patient’s response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline

Authority required

Initial or re-Treatment [Initial 2. Face, hand, foot (Received prior biological agent under PBS)]

Treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over who:

(a) have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot; and

(b) have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle; and

(c) have not failed PBS-subsidised therapy with infliximab for the treatment of this condition in the current Treatment Cycle.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient’s condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and

(ii) details of prior biological treatment, including dosage, date and duration of treatment.

Applications for patients who have demonstrated a response to PBS-subsidised infliximab treatment within this Treatment Cycle and who wish to re-commence infliximab treatment within the same Cycle following a break in therapy, will only be approved where evidence of the patient’s response to their most recent course of PBS-subsidised infliximab treatment has been submitted to Medicare Australia within 1 month of cessation of treatment.

A maximum of 22 weeks of treatment with infliximab will be authorised under this restriction.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 22 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period beyond 22 weeks.

A PASI assessment of the patient’s response to this course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be
Monday to Friday). Under no circumstances where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment with infliximab will be authorised.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, for a maximum of 24 weeks of treatment with infliximab. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

Patients who fail to demonstrate a response to treatment with infliximab, as defined in the Authority Applications, are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may re-commence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

**Authority required**

Continuing PBS-subsidised treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over:

(a) who have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot; and
(b) whose most recent course of PBS-subsidised biological treatment for this condition in this Treatment Cycle was with infliximab; and
(c) who have demonstrated an adequate response to treatment with infliximab.

An adequate response to infliximab treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the pre-biological treatment baseline values; or
(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the pre-biological treatment baseline value.

This assessment must be provided to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with infliximab, the assessment of response must be after a minimum of 12 weeks of treatment with an initial course.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and
(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
   (i) the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams along with the date of the assessment of the patient’s condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

The most recent PASI assessment must be no more than 1 month old at the time of application.

A maximum of 24 weeks of treatment with infliximab will be authorised under this restriction. At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for continuing authority applications, or for treatment that would otherwise extend the treatment period beyond 24 weeks.

A PASI assessment of the patient’s response must be conducted within 4 weeks prior to completion of this course of treatment. This assessment, which will be used to determine eligibility for further continuing treatment must be submitted to Medicare Australia no later than 1 month from the date of completion of this course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment.

The PASI assessment for continuing treatment must be performed on the same affected area assessed at baseline.

Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may re-commence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

**Note**

Any queries concerning the arrangements to prescribe infliximab may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe infliximab should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826
TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, etanercept, infliximab, and ustekinumab, for adult patients with severe chronic plaque psoriasis. Therefore, where the term ‘biological agents’ appears in the following NOTES and restrictions, it only refers to adalimumab, etanercept, infliximab, and ustekinumab.

From 1 March 2010, all patients will be able to commence a ‘Biological Treatment Cycle’ (Cycle), where they may trial adalimumab, etanercept, infliximab, or ustekinumab without having to meet the initial treatment criteria, that is they will not need to experience a disease flare when swapping to an alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

A patient who received PBS-subsidised biological agent treatment for chronic plaque psoriasis prior to 1 March 2010 is considered to be in their first Cycle as of 1 March 2010.

Patients are eligible for PBS-subsidised treatment with only 1 biological agent at any 1 time.

Within the same Treatment Cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for a PBS-subsidised biological agent, they must change to an alternate agent if they wish to continue PBS-subsidised biological treatment. A patient who, prior to 1 March 2010, was authorised to receive PBS-subsidised initial treatment for chronic plaque psoriasis with the same agent twice, is exempt from this condition in respect of applications approved prior to 1 March 2010.

Patients must be assessed for response to each course of continuing treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a Treatment Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological agent therapy before they are eligible to commence the next Cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological agent treatment in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Treatment Cycle.

Patients for whom a break in PBS-subsidised therapy of less than 5 years duration has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle.

There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe chronic plaque psoriasis after 1 March 2010.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands, and feet.

(1) Application for approval for initial treatment.

Applications for a course of initial treatment should be made in the following situations:

(i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); or

(ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under ‘(4) Swapping therapy’ below]; or

(iii) patients who wish to re-commence treatment following a break in PBS-subsidised therapy with that agent (Initial 2).

All applications for initial treatment will be limited to provide for a maximum of 16 weeks of treatment in the case of adalimumab and etanercept, 22 weeks of treatment in the case of infliximab and 28 weeks of treatment in the case of ustekinumab.

(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological agent, a PASI assessment must be conducted after at least 12 weeks of treatment. This assessment must be submitted to Medicare Australia within 1 month of the completion of this initial treatment course. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

(3) Application for continuing treatment.

Following the completion of an initial treatment course of a biological agent to which an adequate response has been demonstrated, patients may qualify to receive up to 24 weeks of continuing treatment with that biological agent. Patients are eligible to continue to receive continuous treatment with 24 week courses providing they continue to sustain a response.

For second and subsequent courses of PBS-subsidised treatment with adalimumab, etanercept, infliximab or ustekinumab it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Where a response assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to sustain a response to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

(4) Swapping therapy.
Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate agent within the same Treatment Cycle without having to requalify with respect to disease severity (i.e. a PASI score of greater than 15), or prior treatment requirements.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

Patients may trial an alternate biological agent at any time, regardless of whether they are receiving therapy with a biological agent at the time of the application or not. However, they cannot swap to a particular agent if they have failed to respond to treatment with that particular agent within the same Cycle.

Patients who commenced treatment with adalimumab prior to 1 June 2009 or ustekinumab prior to 1 March 2010 access these interchangeability arrangements in the same way as patients who have not.

To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the agent being ceased.

(5) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment authority is submitted within a Treatment Cycle and subsequent response will be assessed according to this revised PASI score.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatment applications.

(6) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

Patients who wish to trial a second or subsequent Biological Treatment Cycle, following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment according to the criteria of the relevant restriction and index of disease severity. Patients must have had at least 1 prior treatment, as listed in the criteria, for a minimum of 6 weeks, and must have a PASI assessment conducted preferably whilst still on treatment, but no later than 1 month following cessation of treatment. The PASI assessment must be no older than 1 month at the time of application.

Note
No applications for increased repeats will be authorised.

5758C
infliximab 100 mg injection, 1 x 100 mg vial 1 .. .. 751.70 Remicade JC

INFLIXIMAB

Authority required

Initial 1

Initial treatment of complex refractory FISTULISING CROHN DISEASE.

Initial PBS-subsidised treatment with infliximab by a gastroenterologist or a consultant physician as specified in the NOTE below, of a patient with complex refractory fistulising Crohn disease who:

(a) has confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician as specified in the NOTE below; and

(b) has an externally draining enterocutaneous or rectovaginal fistula; and

(c) has signed a patient acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criteria for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

Authority applications must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Fistulising Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) a completed current Fistula Assessment Form including the date of assessment of the patient’s condition; and

(ii) a signed patient acknowledgement.

The most recent fistula assessment must be no more than 1 month old at the time of application.

A maximum quantity and number of repeats to provide for an initial course of infliximab consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6 will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete 3 doses of infliximab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

An assessment of the patient’s response to this initial course of treatment must be made up to 12 weeks after the first dose (up to 6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.
Authority required

Initial 3 (grandfather)

Initial PBS-subsidised treatment of complex refractory fistulising Crohn disease in a patient who has previously received non-PBS-subsidised infliximab.

Initial PBS-subsidised supply for continuing treatment with infliximab by a gastroenterologist, a consultant physician as specified in the NOTE below, or other consultant physician in consultation with a gastroenterologist of a patient who satisfies the following criteria:

(a) has a documented history of complex refractory fistulising Crohn disease; and
(b) had a draining enterocutaneous or rectovaginal fistula(e) prior to commencing treatment with infliximab; and
(c) has not failed PBS-subsidised treatment with infliximab for this condition more than once in the current treatment cycle.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians (internal medicine specialising in gastroenterology (code 81)) or consultant physicians (general medicine specialising in gastroenterology (code 82)).

To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of TNF-alfa antagonist therapy within the timeframes specified in the relevant restriction.

Where the most recent course of PBS-subsidised TNF-alfa antagonist treatment was approved under an initial treatment restriction, the patient must have been assessed for response to that course following a minimum of 12 weeks therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

If the response assessment to the previous course of TNF-alfa antagonist treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of TNF-alfa antagonist.

Authority applications must be made in writing and must include:

(a) a completed authority prescription form; and
(b) a completed Fistulising Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
   (i) a completed current Fistula Assessment Form including the date of assessment of the patient’s condition; and
   (ii) details of prior TNF-alfa antagonist treatment including details of date and duration of treatment.

The most recent fistula assessment must be no more than 1 month old at the time of application.

A maximum quantity and number of repeats to provide for an initial course of infliximab consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete 3 doses of infliximab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

An assessment of the patient’s response to this initial course of treatment must be made up to 12 weeks after the first dose (up to 6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

This assessment must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment.
An adequate response to infliximab treatment is defined as:

(a) a decrease from baseline in the number of open draining fistulae of greater than or equal to 50%; and/or

(b) a marked reduction in drainage of all fistula(e) from baseline, together with less pain and induration as reported by the patient.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Fistulising Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) a completed current and baseline Fistula Assessment form including the date of assessment of the patient’s condition; and

(ii) a signed patient acknowledgement.

The current fistula assessment must be no more than 1 month old at the time of application.

The baseline fistula assessment must be from immediately prior to commencing treatment with infliximab.

An assessment of the patient’s response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criteria.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with infliximab.

Patients are eligible to receive continuing infliximab treatment in courses of up to 24 weeks providing they continue to sustain the response.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised. No applications for increased repeats will be authorised.

Where fewer than 2 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Patients may qualify for PBS-subsidised treatment under this restriction once only

**Authority required**

Continuing treatment of complex refractory FISTULISING CROHN DISEASE.

Continuing PBS-subsidised treatment with infliximab by a gastroenterologist, a consultant physician as specified in the NOTE below or other consultant physician in consultation with a gastroenterologist, of a patient who:

(a) has a documented history of complex refractory fistulising Crohn disease; and

(b) has demonstrated or sustained an adequate response to treatment with infliximab.

NOTE: Prescribers must be gastroenterologists [code 87], consultant physicians [general medicine specialising in gastroenterology [code 81]] or consultant physicians [general medicine specialising in gastroenterology [code 82]].

An adequate response is defined as:

(a) a decrease from baseline in the number of open draining fistulae of greater than or equal to 50%; and/or

(b) a marked reduction in drainage of all fistula(e) from baseline, together with less pain and induration as reported by the patient.

Authority applications must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Fistulising Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes a completed Fistula Assessment form including the date of the assessment of the patient’s condition.

The fistula assessment must be no more than 1 month old at the time of application.

If the application is the first application for continuing treatment with infliximab, an assessment of the patient’s response must be made up to 12 weeks after the first dose so that there is adequate time for a response to be demonstrated.

An assessment of the patient’s response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criteria.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with infliximab.

Patients are eligible to receive continuing infliximab treatment in courses of up to 24 weeks providing they continue to sustain the response.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised. No applications for increased repeats will be authorised.

Where fewer than 2 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday)

**Note**

Any queries concerning the arrangements to prescribe infliximab may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised TNF-alfa antagonist more than a 5-year break is measured from the date of the last approval for PBS-subsidised TNF-alfa antagonist treatment in the most recent cycle to the date of the commencement of a new treatment cycle.

A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of more than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of less than 5 years, may first application for initial treatment with a TNF-alfa antagonist under the new treatment cycle.

For second and subsequent courses of PBS-subsidised TNF-alfa antagonist treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Adalimumab only: Two completed authority prescriptions must be submitted with every initial application for adalimumab. One prescription must be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats. The second prescription must be written for 2 doses of 40 mg and 2 repeats.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific TNF-alfa antagonist, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing TNF-alfa antagonist treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted TNF-alfa antagonist supply.

TREATMENT OF COMPLEX REFRACTORY FISTULISING CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab and infliximab for patients with complex refractory fistulising Crohn disease. Where the term 'tumour necrosis factor (TNF) alfa antagonist' appears in the following NOTES and restrictions, it refers to adalimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 2 TNF-alfa antagonists at any 1 time.

From 1 April 2011, under the PBS, all patients will be able to commence a treatment cycle where they may have trial each PBS-subsidised TNF-alfa antagonist without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a TNF-alfa antagonist while they continue to show a response to therapy.

A patient who received PBS-subsidised TNF-alfa antagonist treatment prior to 1 April 2011 is considered to be in their first cycle as of 1 April 2011. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised TNF-alfa antagonist more than twice.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised TNF-alfa antagonist therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised TNF-alfa antagonist treatment in the most recent cycle to the date of the first application for initial treatment with a TNF-alfa antagonist under the new treatment cycle.

A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised TNF-alfa antagonist therapy after 1 April 2011.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised TNF-alfa antagonist treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) TNF-alfa antagonist therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to re-commence treatment with a specific TNF-alfa antagonist following a break in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks of therapy for infliximab.

From 1 April 2011, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

For second and subsequent courses of PBS-subsidised TNF-alfa antagonist treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Adalimumab only: Two completed authority prescriptions must be submitted with every initial application for adalimumab. One prescription must be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats. The second prescription must be written for 2 doses of 40 mg and 2 repeats.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific TNF-alfa antagonist, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing TNF-alfa antagonist treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted TNF-alfa antagonist supply.
Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised TNF-alfa antagonist is approved, a patient may swap if eligible to the alternate TNF-alfa antagonist within the same treatment cycle.

A patient may trial the alternate TNF-alfa antagonist at any time, regardless of whether they are receiving therapy (initial or continuing) with a TNF-alfa antagonist at the time of the application. However, they cannot swap to a particular TNF-alfa antagonist if they have failed to respond to prior treatment with that drug two times within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to the alternate TNF-alfa antagonist should be accompanied by the approved authority prescription or remaining repeats for the TNF-alfa antagonist the patient is ceasing.

(3) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements submitted with the first authority application for a TNF-alfa antagonist. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and Medicare Australia will assess response according to these revised baseline measurements.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised TNF-alfa antagonist therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity.

(5) Patients 'grandfathered' onto PBS-subsidised treatment with adalimumab or infliximab.

A patient who commenced treatment with adalimumab for complex refractory fistulising Crohn disease prior to 4 November 2010 or infliximab prior to 1 March 2010 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 'grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with adalimumab or infliximab will be authorised under this criterion.

Following completion of the initial PBS-subsidised course, further applications for treatment with adalimumab or infliximab will be assessed under the continuing treatment restriction.

'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must requalify for initial treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' above for further details.

9654D infliximab 100 mg injection, 1 x 100 mg vial 1 .. .. 751.70 Remicade JC

**Interleukin inhibitors**

**TOCILIZUMAB**

**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 12 months)

**Clinical criteria:**

Patient must have severe active juvenile idiopathic arthritis,

AND

Patient must have received no prior PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition; OR

Patient must not have received PBS-subsidised treatment with adalimumab, etanercept or tocilizumab for this condition in the previous 12 months,

AND

Patient must have demonstrated severe intolerance of, or toxicity due to, methotrexate; OR

Patient must have demonstrated failure to achieve an adequate response to 1 or more of the following treatment regimens: (i) oral or parenteral methotrexate at a dose of at least 20 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; or (ii) oral methotrexate at a dose of at least 10 mg per square metre weekly together with at least 1 other disease modifying anti-rheumatic drug (DMARD), alone or in combination with corticosteroids, for a minimum of 3 months,

AND

Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

Patient must be under 18 years of age and a parent or authorised guardian must have signed a patient acknowledgement.

**Treatment criteria:**
### HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>Qty $</th>
<th>Brand Name and Manufacturer</th>
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**Must be treated by a paediatric rheumatologist; OR**

Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.

Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.

Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis.

If treatment with methotrexate alone or in combination with another DMARD is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

(a) an active joint count of at least 20 active (swollen and tender) joints; OR

(b) at least 4 active joints from the following list:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count assessment must be performed preferably whilst still on DMARD treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

The authority application must be made in writing and must include:

(1) completed authority prescription form(s); and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form; and

(3) an acknowledgement signed by a parent or authorised guardian.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

If a patient fails to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle. A patient may re-trial tocilizumab after a minimum of 12 months have elapsed between the date the last PBS-subsidised bDMARD was stopped and the date of the first application under a new treatment cycle.

**Note**

Use of alternative DMARDs in children is dependent on approval by the Therapeutic Goods Administration as age restrictions may apply.

**Note**

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient who has severe active juvenile idiopathic arthritis. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.

From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised biological therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 12 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 12 months may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 12 months (Initial 1); or

(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (initial 2) [further details are under ‘Swapping therapy’ below]; or

(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 12 months in PBS-subsidised therapy with that agent (initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 12 months.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.

(4) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 12 months, must requalify for treatment under the Initial 1 treatment restriction.

(5) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with bDMARDs should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to the Department of Human Services at the time treatment is ceased.

**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after break of less than 12 months)

**Clinical criteria:**

Patient must have a documented history of severe active juvenile idiopathic arthritis,

AND

Patient must have received prior PBS-subsidised treatment with adalimumab, etanercept or tocilizumab for this condition in this treatment cycle,

AND

Patient must not have failed PBS-subsidised therapy with tocilizumab for this condition in the current treatment cycle,

AND

Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

Patient must be under 18 years of age.

**Treatment criteria:**

Must be treated by a paediatric rheumatologist; OR

Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.

The authority application must be made in writing and must include:

(1) completed authority prescription form(s); and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

Applications for a patient who has received PBS-subsidised treatment with tocilizumab in this treatment cycle and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised tocilizumab treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised tocilizumab treatment was approved under either of the Initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.
Where the most recent course of PBS-subsidised tocilizumab treatment was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab.

If a patient fails to respond to PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Note
Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Note
TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient who has severe active juvenile idiopathic arthritis. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.

From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised biological therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 12 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 12 months may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.

(a) Initial treatment.
Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment in this current treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 12 months (Initial 1); or

(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or

(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 12 months in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 12 months.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.

(4) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 12 months, must requalify for treatment under the Initial 1 treatment restriction.

(5) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with bDMARDS should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to the Department of Human Services at the time treatment is ceased.

**Authority required**

Severe active juvenile idiopathic arthritis

**Clinical criteria:**

Patient must have received insufficient tocilizumab therapy under the Initial 1 (new patient or patient recommencing treatment after break of more than 12 months) restriction to complete 16 weeks treatment; OR

Patient must have received insufficient tocilizumab therapy under the Initial 2 (change or recommencement of treatment after break of less than 12 months) restriction to complete 16 weeks treatment.
The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Treatment criteria:**
Must be treated by a paediatric rheumatologist; OR
Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

**Note**
Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

**Authority required**
Severe active juvenile idiopathic arthritis
Treatment Phase: Continuing treatment

**Clinical criteria:**
Patient must have a documented history of severe active juvenile idiopathic arthritis,

AND
Patient must have demonstrated an adequate response to treatment with tocilizumab,

AND
Patient must have received tocilizumab as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment in this treatment cycle,

AND
Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

**Treatment criteria:**
Must be treated by a rheumatologist; OR
Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurement of joint count submitted with the initial treatment application.

The authority application must be made in writing and must include:

(1) completed authority prescription form(s); and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient
drug, based on the weight of the patient, for one infusion. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 5 repeats will be authorised.

All applications for continuing treatment with tocilizumab must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with tocilizumab, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab.

If a patient fails to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle.

**Note**

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

**Note**

TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient who has severe active juvenile idiopathic arthritis. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.

From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and must have, at a minimum, a 12 month break in PBS-subsidised biological therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 12 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 12 months may commence a further course of treatment within the same treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 12 months (Initial 1); or

(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or

(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 12 months in PBS-subsidised therapy with
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.

(4) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 12 months, must requalify for treatment under the initial 1 treatment restriction.

(5) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with bDMARDs should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to the Department of Human Services at the time treatment is ceased.

**Authority required**

Severe active juvenile idiopathic arthritis

**Clinical criteria:**

Patient must have received insufficient tocilizumab therapy under the Continuing Treatment restriction to complete 24 weeks treatment, AND

The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Treatment criteria:**

Must be treated by a rheumatologist; OR

Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

**Note**

Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:

Department of Human Services
HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

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TOCILIZUMAB

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months)

Clinical criteria:

Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years, AND

Patient must have received no PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition in the previous 24 months; OR

Patient must have received no PBS-subsidised bDMARD treatment for at least 5 years if they failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) in their last treatment cycle, AND

Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulphasalazine at a dose of at least 2 g daily; OR

Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulphasalazine at a dose of at least 2 g daily; OR

Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulphasalazine are contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above, must include at least 3 months continuous treatment with each of at least 2 DMARDs, with one or more of the following DMARDs being used in place of the DMARDs which are contraindicated or not tolerated: (i) azathioprine at a dose of at least 1 mg/kg per day; and/or (ii) cyclosporin at a dose of at least 2 mg/kg/day; and/or (iii) sodium aurothiomalate at a dose of 50 mg weekly, AND

Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

For the purposes of this restriction ‘biological disease modifying anti-rheumatic drug’ and ‘bDMARD’ mean adalimumab, etanercept or tocilizumab.
The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

(a) an active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(1) completed authority prescription form(s); and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form; and

(3) a signed patient acknowledgement.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

If a patient fails to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle. A patient may re-trial tocilizumab after a minimum of 5 years have elapsed between the date of the last approval for PBS-subsidised bDMARD therapy in the last treatment cycle and the date of the first application under a new treatment cycle.

Note

The Department of Human Services website (www.humanservices.gov.au) has details of the toxicities, including severity, which will be accepted for the following purposes:

(a) exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose;

(b) substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial;

(c) exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy.

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826
TREATMENT OF ADULT PATIENTS WITH A HISTORY OF JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient over 18 years who has a history of juvenile idiopathic arthritis with onset prior to the age of 18 years. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.

From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 5 year break in PBS-subsidised bDMARD therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date of the last approval for PBS-subsidised bDMARD therapy in the last treatment cycle to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 24 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 24 months may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 24 months must commence a new treatment cycle. The length of the break in therapy is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised bDMARD therapy of more than 24 months (Initial 1); or

(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or

(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

A patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count and ESR/CRP) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months.

Note

TREATMENT OF ADULT PATIENTS WITH A HISTORY OF JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient over 18 years who has a history of juvenile idiopathic arthritis with onset prior to the age of 18 years. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.

From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 5 year break in PBS-subsidised bDMARD therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date of the last approval for PBS-subsidised bDMARD therapy in the last treatment cycle to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 24 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 24 months may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 24 months must commence a new treatment cycle. The length of the break in therapy is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised bDMARD therapy of more than 24 months (Initial 1); or

(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or

(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

A patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count and ESR/CRP) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months.
A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.

(4) Re-commencement of treatment after a 24 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 24 months, must requalify for treatment under the Initial 1 treatment restriction.

**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after break of less than 24 months)

**Clinical criteria:**

Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years,

AND

Patient must have received prior PBS-subsidised treatment with adalimumab, etanercept or tocilizumab for this condition in this treatment cycle,

AND

Patient must not have failed PBS-subsidised therapy with tocilizumab for this condition in the current treatment cycle,

AND

Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

Patient must be aged 18 years or older.

**Treatment criteria:**

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.

The authority application must be made in writing and must include:

(1) completed authority prescription form(s); and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

Applications for a patient who has received PBS-subsidised treatment with tocilizumab in this treatment cycle and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised tocilizumab treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised tocilizumab treatment was approved under either of the Initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised tocilizumab treatment was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab.
An adequate response to treatment is defined as:

- an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;
- and either of the following:
  - (a) an active joint count of fewer than 10 active (swollen and tender) joints; or
  - (b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or
- (c) a reduction in the number of the following active joints, from at least 4, by at least 50%:
  - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
  - (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Note

TREATMENT OF ADULT PATIENTS WITH A HISTORY OF JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient over 18 years who has a history of juvenile idiopathic arthritis with onset prior to the age of 18 years. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.

From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

- (i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and
- (ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 5 year break in PBS-subsidised bDMARD therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date of the last approval for PBS-subsidised bDMARD therapy in the last treatment cycle to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 24 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 24 months may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 24 months must commence a new treatment cycle. The length of the break in therapy is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.

(a) Initial treatment.

Applications for initial treatment should be made where:

- (i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
- (ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
- (iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
- (iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).
A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current course of treatment.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

A patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count and ESR/CRP) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.

(4) Re-commencement of treatment after a 24 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 24 months, must requalify for treatment under the initial 1 treatment restriction.

**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months) or Initial 2 (change or recommencement of treatment after break of less than 24 months) – balance of supply

**Clinical criteria:**

Patient must have received insufficient tocilizumab therapy under the Initial 1 (new patient or patient recommencing treatment after break of more than 24 months) restriction to complete 16 weeks treatment; OR

Patient must have received insufficient tocilizumab therapy under the Initial 2 (change or recommencement of treatment after break of less than 24 months) restriction to complete 16 weeks treatment,

**AND**

The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Treatment criteria:**

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Note**

Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs
Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment

**Clinical criteria:**
- Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years,
- Patient must have demonstrated an adequate response to treatment with tocilizumab,
- Patient must have received tocilizumab as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment in this treatment cycle,
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

**Population criteria:**
- Patient must be aged 18 years or older.

**Treatment criteria:**
- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.

An adequate response to treatment is defined as:
- an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;
- AND either of the following:
  (a) an active joint count of fewer than 10 active (swollen and tender) joints; or
  (b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or
  (c) a reduction in the number of the following active joints, from at least 4, by at least 50%:
    (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
    (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) completed authority prescription form(s); and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 5 repeats will be authorised.

All applications for continuing treatment with tocilizumab must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with tocilizumab, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to
A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 24 months must commence a further course of treatment within the same treatment cycle.

If a patient fails to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle.

Note
Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prior Written Approval of Complex Drugs

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Note
TREATMENT OF ADULT PATIENTS WITH A HISTORY OF JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient over 18 years who has a history of juvenile idiopathic arthritis with onset prior to the age of 18 years. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.

From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 5 year break in PBS-subsidised bDMARD therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date of the last approval for PBS-subsidised bDMARD therapy in the last treatment cycle to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in PBS-subsidised treatment of at least 24 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 24 months may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 24 months must commence a new treatment cycle. The length of the break in therapy is measured from the date the most recent treatment with PBS-subsidised bDMARD therapy was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or

(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or

(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

A patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count and ESR/CRP) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.

(4) Re-commencement of treatment after a 24 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 24 months, must requalify for treatment under the Initial 1 treatment restriction.

**Authority required**

Severe active juvenile idiopathic arthritis

**Treatment Phase: Continuing Treatment – balance of supply**

**Clinical criteria:**

Patient must have received insufficient tocilizumab therapy under the Continuing Treatment restriction to complete 24 weeks treatment, AND

The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Treatment criteria:**

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Note**

Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

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**TOCILIZUMAB**

**Authority required**
Assessment of a patient's response to an initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

The baseline measurements of joint count, fever and/or CRP level and platelet count must be performed preferably whilst on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

The authority application must be made in writing and must include:

(i) the date of assessment of severe active systemic juvenile idiopathic arthritis;

(ii) details of prior treatment including dose and duration of treatment;

(iii) pathology reports detailing CRP and platelet count where appropriate; and

(iv) a completed guardian acknowledgement form.

The most recent systemic juvenile idiopathic arthritis assessment must be no more than 1 month old at the time of application. A maximum of 16 weeks of treatment will be authorised under this restriction.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for two infusions (one month supply). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

Where fewer than 3 repeats are requested at the time of initial application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Assessment of a patient's response to an initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted...
If a patient fails to respond to 2 courses of treatment in a treatment cycle they will not be eligible to receive further PBS-subsidised tocilizumab therapy in that treatment cycle. A patient may re-trial tocilizumab after a minimum of 12 months have elapsed between the date the last PBS-subsidised treatment was stopped and the date of the first application under a new treatment cycle.

**Authority required**

Initial 2 (retrial or recommencement of treatment after a break of less than 12 months)

Initial PBS-subsidised treatment by a rheumatologist, or under the supervision of a paediatric rheumatology treatment centre, of a patient who:

(a) has a documented history of systemic juvenile idiopathic arthritis; AND

(b) has received PBS-subsidised treatment with tocilizumab for this condition in the previous 12 months; AND

(c) has not failed PBS-subsidised therapy with tocilizumab for this condition more than once in the current treatment cycle.

The authority application must be made in writing and must include:

(1) completed authority prescription form(s); and

(2) a completed Systemic Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) pathology reports detailing CRP and platelet count where appropriate.

Applications for a patient who has received PBS-subsidised treatment with tocilizumab in this treatment cycle and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient’s most recent course of PBS-subsidised tocilizumab treatment, within the timeframes specified below.

A maximum of 16 weeks of treatment will be authorised under this restriction.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for two infusions (one month supply). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

Where fewer than 3 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with tocilizumab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

An assessment of the patient’s response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criteria. Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with tocilizumab.

Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to that course of tocilizumab.

If a patient fails to respond to 2 courses of treatment they will not be eligible to receive further PBS-subsidised tocilizumab therapy in this treatment cycle. A patient may re-trial tocilizumab after a minimum of 12 months have elapsed between the date the last PBS-subsidised treatment was stopped and the date of the first application under a new treatment cycle.

**Authority required**

Initial 3 (‘grandfather’ patients)

Initial treatment by a rheumatologist, or under the supervision of a paediatric rheumatology treatment centre, of a patient who:

(a) has a documented history of systemic juvenile idiopathic arthritis; and

(b) was receiving treatment with tocilizumab prior 1 November 2011; and

(c) has demonstrated a response as specified in the criteria for continuing PBS-subsidised treatment with tocilizumab; and

(d) is receiving treatment with tocilizumab at the time of application.

To ensure consistency in determining response, the same indices of disease severity used to establish the baseline must be provided for all subsequent continuing treatment applications.

The authority application must be made in writing and must include:

(1) completed authority prescription form(s); and

(2) a completed Systemic Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) pathology reports detailing CRP and platelet count where appropriate; and

(3) a signed patient or authorised guardian acknowledgement form.

The most recent systemic juvenile idiopathic arthritis assessment must be no more than 1 month old at the time of application.

The baseline systemic juvenile idiopathic arthritis assessment must be provided and must be from immediately prior to commencing treatment with tocilizumab. (See NOTE (3) above for definition of baseline measurements to determine response.)

An assessment of the patient’s response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criteria.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to
Patients are eligible to receive continuing tocilizumab treatment in courses of up to 24 weeks providing they continue to sustain the response. At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for two infusions (one month supply). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 5 repeats will be authorised.

Where fewer than 5 repeats are initially requested with the authority prescription, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

A patient may only qualify for PBS-subsidised treatment under this restriction once

**Authority required**

Continuing treatment

Continuing treatment with tocilizumab, by a rheumatologist or under the supervision of a paediatric rheumatology treatment centre, of a patient who:

(a) has a documented history of systemic juvenile idiopathic arthritis; AND

(b) has demonstrated an adequate response to treatment with tocilizumab.

An adequate response to treatment is defined as:

(a) in a patient with polyarticular course disease:

(i) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(ii) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

— elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

— shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

(b) in a patient with refractory systemic symptoms:

(i) absence of fever greater than 38 degrees Celsius in the preceding seven days; AND/OR

(ii) a reduction in the CRP level and platelet count by at least 30% from baseline; AND/OR

(iii) a reduction in the dose of corticosteroid by at least 30% from baseline.

The authority application must be made in writing and must include:

(1) completed authority prescription form(s); and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) baseline and current pathology reports detailing CRP and platelet count where appropriate.

The most recent systemic juvenile idiopathic arthritis assessment must be no more than 1 month old at the time of application.

Where the most recent course of PBS-subsidised tocilizumab treatment was approved under the Initial treatment restriction, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be provided to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised tocilizumab treatment was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Patients are eligible to receive continuing tocilizumab treatment in courses of up to 24 weeks providing they continue to sustain the response. At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for two infusions (one month supply). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 5 repeats will be authorised.

Where fewer than 5 repeats are requested at the time of initial application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

If a patient fails to respond to 2 courses of treatment they will not be eligible to receive further PBS-subsidised tocilizumab therapy in this treatment cycle. A patient may re-trial tocilizumab after a minimum of 12 months have elapsed between the date the last PBS-subsidised treatment was stopped and the date of the first application under a new treatment cycle

**Note**

Any queries concerning the arrangements to prescribe tocilizumab may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Further prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe tocilizumab should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs
TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying anti-rheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab) and the T-cell co-stimulation modulator (abatacept).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is re-assessed for response to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact Medicare Australia on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab and tocilizumab, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to Medicare Australia within 4 weeks.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:

Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.
Patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of abatacept every 24 weeks providing there is no evidence of disease progression. Patients who do not complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

Rituximab patients:

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent. A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept patients:

Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for eligibility to every course of treatment approved, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have been previously treated with rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

**Note**

(3) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and Medicare Australia will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

**Note**

TREATMENT OF PATIENTS WITH SEVERE ACTIVE SYSTEMIC JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of tocilizumab for a patient who has severe active systemic juvenile idiopathic arthritis (sJIA).

From 1 May 2012, a patient receiving PBS-subsidised tocilizumab therapy is considered to be in a treatment cycle. Under these arrangements,
within a single treatment cycle, a patient may:

— continue to receive long-term treatment with PBS-subsidised tocilizumab while they continue to show a response to therapy, and
— fail to respond, or to sustain a response, to PBS-subsidised tocilizumab twice.

Once a patient has either failed or ceased to respond to 2 courses of treatment, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised tocilizumab therapy before they are eligible to receive further PBS-subsidised tocilizumab therapy. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised tocilizumab treatment was stopped to the date of the first application for initial treatment with tocilizumab under the new treatment cycle.

A patient who was receiving PBS-subsidised tocilizumab treatment immediately prior to 1 May 2012 is considered to be in their first cycle as of 1 May 2012. A patient who has had a break in tocilizumab treatment of at least 12 months immediately prior to making a new application, on or after 1 May 2012, will commence a new treatment cycle.

A patient who has failed their first course of tocilizumab in a treatment cycle and who has a break in therapy of less than 12 months may commence a second course of treatment within the same treatment cycle.

A patient who has failed their first course of tocilizumab in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle.

(1) How to prescribe PBS-subsidised tocilizumab therapy after 1 May 2012.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised tocilizumab treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
(ii) a patient wishes to re-commence treatment with tocilizumab following a break in PBS-subsidised therapy of more than 12 months (Initial 1); or
(iii) a patient has received the first course of PBS-subsidised (initial or continuing) tocilizumab therapy in a treatment cycle and is deemed to have failed to respond or sustain a response and the treating physician wishes to trial a second course (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab for that course.

For second and subsequent courses of PBS-subsidised tocilizumab, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with tocilizumab, a patient may qualify to receive up to 24 weeks of continuing treatment with tocilizumab providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing tocilizumab treatment in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted tocilizumab supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab.

(2) Treatment cycle.

Once initial treatment with PBS-subsidised tocilizumab is approved, a patient deemed to have failed to respond to the first course of treatment may have a second course without having to requalify with respect to the indices of disease severity (joint count, fever and/or CRP level and platelet count) or the prior therapy requirements, except if the patient has had a break in therapy of more than 12 months.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

(3) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the relevant baseline measurements of the joint count, fever and/or CRP level and platelet count submitted with the first authority application for tocilizumab.

Where a patient is deemed to have failed to respond or to sustain a response to the first course of therapy in a treatment cycle, prescribers may provide new baseline measurements for the second course of treatment within that cycle. Medicare Australia will assess response according to these revised baseline measurements. If new baseline measurements are not submitted with the initial application for the second course of treatment, then those submitted with the first course will be used by Medicare Australia to assess response to the second course.

(4) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised tocilizumab therapy of at least 12 months, must requalify for treatment under the Initial 1 treatment restriction.

(5) Patients ‘grandfathered’ onto PBS-subsidised treatment with tocilizumab.

A patient who commenced treatment with tocilizumab for severe active systemic juvenile idiopathic arthritis prior to 1 November 2011 and who continues to receive treatment at the time of application, may qualify for treatment under the initial ‘grandfather’ treatment restriction.
A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with tocilizumab will be authorised under this criterion.

Following completion of the initial PBS-subsidised course, further applications for treatment with tocilizumab will be assessed under the continuing treatment restriction.

‘Grandfather’ arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a ‘grandfather’ patient must qualify for initial treatment under the criteria that apply to a new patient. See ‘Re-commencement of treatment after a 12 month break in PBS-subsidised therapy’ above for further details.

(6) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with tocilizumab should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to Medicare Australia at the time treatment is ceased.

**Note**

Special Pricing Arrangements apply.

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**TOCILIZUMAB**

**Authority required**

Initial 1 (new patient or patient re-commencing after a break of more than 24 months)

Initial PBS-subsidised treatment with tocilizumab, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults who:

(a) have severe active rheumatoid arthritis; and

(b) have received no PBS-subsidised treatment with a bDMARD for this condition in the previous 24 months; and

(c) have failed, in the 24 months immediately prior to the date of application, to achieve an adequate response to at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs), which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be:

— hydroxychloroquine at a dose of at least 200 mg daily; or

— leflunomide at a dose of at least 10 mg daily; or

— sulfasalazine at a dose of at least 2 g daily.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, then the 6 months of intensive DMARD treatment must include at least 3 months continuous treatment with each of at least 2 of the DMARDs:

— hydroxychloroquine at a dose of at least 200 mg daily; and/or

— leflunomide at a dose of at least 10 mg daily; and/or

— sulfasalazine at a dose of at least 2 g daily.

The application must include details of the contraindication or intolerance to methotrexate. Details of the toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose can be found on the Medicare Australia website [www.medicareaustralia.gov.au]. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

If 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved product information or cannot be tolerated at the doses specified above, then one or more of the following DMARDs may be used in place of these agents in order to satisfy the requirement for a trial of 6 months of intensive DMARD therapy with at least 2 DMARDs taken continuously for at least 3 months each:

— azathioprine at a dose of at least 1 mg/kg per day; and/or

— cyclosporin at a dose of at least 2 mg/kg/day; and/or

— sodium aurothiomalate at a dose of 50 mg weekly.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances. Details of the toxicities, including severity, which will be accepted as a reason for substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial can be found on the Medicare Australia website [www.medicareaustralia.gov.au].

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance and dose for each DMARD must be provided in the authority application. Details of the toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy can be found on the Medicare Australia website [www.medicareaustralia.gov.au].

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial

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**HIGHERLY SPECIALISED DRUGS PROGRAM (Public Hospital)**

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an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

(i) a total active joint count of at least 20 active (swollen and tender) joints; or

(ii) at least 4 active joints from the following list of major joints:

— elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

— shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and

(3) a signed patient acknowledgement.

A maximum of 16 weeks of treatment will be authorised under this restriction.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials of appropriate strength, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 8 mg per kg. A separate authority prescription form must be completed for each strength requested.

Up to a maximum of 3 repeats of each strength may be authorised. Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Assessment of a patient's response to an initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab.

Patients who fail to demonstrate a response to treatment with tocilizumab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**Authority required**

Initial 2 (change or re-commencement after break of less than 24 months)

Initial course of PBS-subsidised treatment with tocilizumab, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults who:

(a) have a documented history of severe active rheumatoid arthritis; and

(b) have received prior PBS-subsidised bDMARD treatment for this condition and are eligible to receive further bDMARD therapy.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

Applications for patients who have received PBS-subsidised treatment with tocilizumab and who wish to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised tocilizumab treatment, within the timeframes specified below.

A maximum of 16 weeks of treatment will be authorised under this restriction.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials of appropriate strength, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 8 mg per kg. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats of each strength may be authorised.

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Where the most recent course of PBS-subsidised tocilizumab treatment was approved under either of the initial 1 or 2 treatment restrictions, patients must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be provided to Medicare Australia no later than 4 weeks from the date that course was ceased.
Where the most recent course of PBS-subsidised tocilizumab treatment was approved under the continuing treatment criteria, patients must have been assessed for response, and the assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Patients who fail to demonstrate a response to treatment with tocilizumab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**Authority required**

Continuing treatment

Continuing PBS-subsidised treatment with tocilizumab, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults:

(a) who have a documented history of severe active rheumatoid arthritis; and
(b) who have demonstrated an adequate response to treatment with tocilizumab; and
(c) whose most recent course of PBS-subsidised bDMARD treatment was with tocilizumab.

An adequate response to treatment is defined as:

- an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and/or
- either of the following:
  (i) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
  (ii) a reduction in the number of the following major active joints, from at least 4, by at least 50%:
    — elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
    — shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The authority application must be made in writing and must include:

1. A completed authority prescription form(s); and
2. A completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

A maximum of 24 weeks of treatment will be approved under this restriction.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials of appropriate strength, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 8 mg per kg. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 5 repeats of each strength may be authorised.

Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

All applications for continuing treatment with tocilizumab must include a measurement of response to the prior course of therapy. This assessment must be provided to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with tocilizumab, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

Patients who fail to demonstrate a response to treatment with tocilizumab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**Note**

Any queries concerning the arrangements to prescribe tocilizumab may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Further prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe tocilizumab should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

**Note**

**TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying anti-rheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab) and the T-cell co-stimulation modulator (abatacept).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

PBS-subsidised abatacept, golimumab, infliximab and rituximab must be used in combination with methotrexate at a dose of at least 7.5 mg weekly. Where a patient cannot tolerate 7.5 mg of methotrexate weekly, they are eligible to receive PBS-subsidised adalimumab, certolizumab pegol, etc.
In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:

- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact Medicare Australia on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or

(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab and tocilizumab, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to Medicare Australia within 4 weeks.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:

Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient’s weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:

A further application may be submitted to Medicare Australia 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response and tolerated therapy.
Calcineurin inhibitors

CYCLOSPORIN

Authority required [STREAMLINED]

3228 Management of rejection in patients following organ or tissue transplantation, under the supervision and direction of a transplant unit. Management includes initiation, stabilisation and review of therapy as required

Authority required [STREAMLINED]

3229 Management (which includes initiation, stabilisation and review of therapy) by dermatologists or clinical immunologists of patients with severe atopic dermatitis for whom other systemic therapies are ineffective or inappropriate
## HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

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**Other immunosuppressants**
LENALIDOMIDE

**Authority required**
Myelodysplastic syndrome

**Treatment Phase:** Initial treatment

**Clinical criteria:**

The treatment must be limited to a maximum duration of 16 weeks,

AND

Patient must be classified as Low risk or Intermediate-1 according to the International Prognostic Scoring System (IPSS),

AND

Patient must have a deletion 5q cytogenetic abnormality with or without additional cytogenetic abnormalities,

AND

Patient must be red blood cell transfusion dependent.

Classification of a patient as Low risk requires a score of 0 on the IPSS, achieved with the following combination: less than 5% marrow blasts with good karyotypic status (normal, -Y alone, -5q alone, -20q alone), and 0/1 cytopenias.

Classification of a patient as Intermediate-1 requires a score of 0.5 to 1 on the IPSS, achieved with the following possible combinations:

1. 5%-10% marrow blasts with good karyotypic status (normal, -Y alone, -5q alone, -20q alone), and 0/1 cytopenias; OR
2. less than 5% marrow blasts with intermediate karyotypic status (other abnormalities), and 0/1 cytopenias; OR
3. less than 5% marrow blasts with good karyotypic status (normal, -Y alone, -5q alone, -20q alone), and 2/3 cytopenias; OR
4. less than 5% marrow blasts with intermediate karyotypic status (other abnormalities), and 2/3 cytopenias; OR
5. 5%-10% marrow blasts with intermediate karyotypic status (other abnormalities), and 0/1 cytopenias; OR
6. 5%-10% marrow blasts with good karyotypic status (normal, -Y alone, -5q alone, -20q alone), and 2/3 cytopenias; OR
7. less than 5% marrow blasts with poor karyotypic status (complex, greater than 3 abnormalities), and 0/1 cytopenias.

Classification of a patient as red blood cell transfusion dependent requires that:

(i) the patient has been transfused within the last 8 weeks; and
(ii) the patient has received at least 8 units of red blood cell in the last 6 months prior to commencing PBS-subsidised therapy with lenalidomide; and would be expected to continue this requirement without lenalidomide treatment.

Patients receiving lenalidomide under the PBS listing must be registered in the i-access risk management program.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and
(b) a completed Myelodysplastic Syndrome Lenalidomide Authority Application - Supporting Information Form; and
(c) a copy of the bone marrow biopsy report demonstrating that the patient has myelodysplastic syndrome; and
(d) a copy of the full blood examination report; and
(e) a copy of the pathology report detailing the cytogenetics demonstrating Low risk or Intermediate-1 disease according to the IPSS (note: using Fluorescence in Situ Hybridization (FISH) to demonstrate MDS-5q is acceptable); and
(f) details of transfusion requirements including: (i) the date of most recent transfusion and the number of red blood cell units transfused; and (ii) the total number of red cell units transfused in the 4 and 6 months preceding the date of this application; and
(g) a signed patient acknowledgement form.

**Note**

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

**Note**

Special Pricing Arrangements apply.

**Authority required**
Myelodysplastic syndrome

**Treatment Phase:** Continuing treatment
**LENALIDOMIDE**

**Authority required**

Multiple myeloma

**Treatment Phase: Initial PBS-subsidised treatment**

**Clinical criteria:**

The condition must be confirmed by a histological diagnosis,

AND

The treatment must be as monotherapy; OR

The treatment must be in combination with dexamethasone,

AND

Patient must have progressive disease after at least one prior therapy,

AND

Patient must have undergone or be ineligible for a primary stem cell transplant,

AND

Patient must have experienced treatment failure after a trial of at least four (4) weeks of thalidomide at a dose of at least 100 mg daily or have failed to achieve at least a minimal response after eight (8) or more weeks of thalidomide-based therapy for progressive disease,

AND

Patient must not be receiving concomitant PBS-subsidised bortezomib.
Progressive disease is defined as at least 1 of the following:

(a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or
(b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or
(c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase of the difference between involved free light chain and uninvolved free light chain; or
(d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or
(e) an increase in the size or number of lytic bone lesions (not including compression fractures); or
(f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or
(g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.

Thalidomide treatment failure is defined as:

(1) confirmed disease progression during thalidomide treatment or within 6 months of discontinuing thalidomide treatment; or
(2) severe intolerance or toxicity unresponsive to clinically appropriate dose adjustment.

Severe intolerance due to thalidomide is defined as unacceptable somnolence or sedation interfering with activities of daily living.

Toxicity from thalidomide is defined as peripheral neuropathy (Grade 2 or greater, interfering with function), drug-related seizures, serious Grade 3 or 4 drug-related dermatological reactions, such as Stevens-Johnson Syndrome, or other Grade 3 or 4 toxicity.

Failure to achieve at least a minimal response after 8 or more weeks of thalidomide-based therapy for progressive disease is defined as:

(1) less than a 25% reduction in serum or urine M protein; or
(2) in oligo-secretory and non-secretory myeloma patients only, less than a 25% reduction in the difference between involved and uninvolved serum free light chain levels.

If the dosing requirement for thalidomide cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and
(2) a completed Multiple Myeloma Lenalidomide Authority Application - Supporting Information Form, which includes details of the histological diagnosis of multiple myeloma, prior treatments including name(s) of drug(s) and date of most recent treatment cycle and record of prior stem cell transplant or ineligibility for prior stem cell transplant; details of thalidomide treatment failure; details of the basis of the diagnosis of progressive disease or failure to respond; and nomination of which disease activity parameters will be used to assess response; and
(3) duration of thalidomide and daily dose prescribed; and
(4) a signed patient acknowledgment.

To enable confirmation of eligibility for treatment, current diagnostic reports of at least one of the following must be provided:

(a) the level of serum monoclonal protein; or
(b) Bence-Jones proteinuria - the results of 24-hour urinary light chain M protein excretion; or
(c) the serum level of free kappa and lambda light chains; or
(d) bone marrow aspirate or trephine; or
(e) if present, the size and location of lytic bone lesions (not including compression fractures); or
(f) if present, the size and location of all soft tissue plasmacytomas by clinical or radiographic examination i.e. MRI or CT-scan; or
(g) if present, the level of hypercalcaemia, corrected for albumin concentration.

As these parameters will be used to determine response, results for either (a) or (b) or (c) should be provided for all patients. Where the patient has oligo-secretory or non-secretory multiple myeloma, either (c) or (d) or if relevant (e), (f) or (g) should be provided. Where the prescriber plans to assess response in patients with oligo-secretory or non-secretory multiple myeloma with free light chain assays, evidence of the oligo-secretory or non-secretory nature of the multiple myeloma (current serum M protein less than 10 g per L) must be provided.

Patients receiving lenalidomide under the PBS listing must be registered in the i-access risk management program.

Note
Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001
**HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)**

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<td>5392.38</td>
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**Note**
Special Pricing Arrangements apply.

**Authority required**

Multiple myeloma

Treatment Phase: Continuing PBS-subsidised treatment

**Clinical criteria:**
Patient must have previously received an authority prescription for lenalidomide,

AND

Patient must not have progressive disease,

AND

The treatment must be as monotherapy; OR

The treatment must be in combination with dexamethasone.

Progressive disease is defined as at least 1 of the following:

(a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or

(b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or

(c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase of the difference between involved free light chain and uninvolved free light chain; or

(d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or

(e) an increase in the size or number of lytic bone lesions (not including compression fractures); or

(f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or

(g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Patients receiving lenalidomide under the PBS listing must be registered in the i-access risk management program.

**Note**
Authority applications for continuing treatment may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Note**
Written applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

**Note**
Special Pricing Arrangements apply.

**RITUXIMAB**

**Authority required**

Initial 1 (patient re-commencing after a break of more than 24 months)

Initial PBS-subsidised treatment with rituximab, in combination with methotrexate at a dose of at least 7.5 mg weekly, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults who:

(a) have severe active rheumatoid arthritis; and

(b) have failed to respond to at least 1 PBS-subsidised TNF-alfa antagonist; and

(c) have received no PBS-subsidised treatment with a bDMARD for this condition in the previous 24 months; and

(d) have failed, in the 24 months immediately prior to the date of application, to achieve an adequate response to at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs), which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be:

— hydroxychloroquine at a dose of at least 200 mg daily; or

Note

Special Pricing Arrangements apply.
If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, then the 6 months of intensive DMARD treatment must include at least 3 months continuous treatment with each of at least 2 of the DMARDs:

- hydroxychloroquine at a dose of at least 200 mg daily; and/or
- leflunomide at a dose of at least 10 mg daily; and/or
- sulfasalazine at a dose of at least 2 g daily.

The application must include details of the contraindication or intolerance to methotrexate. Details of the toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose can be found on the Medicare Australia website [www.medicareaustralia.gov.au]. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

If 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved product information or cannot be tolerated at the doses specified above, then one or more of the following DMARDs may be used in place of these agents in order to satisfy the requirement for a trial of 6 months of intensive DMARD therapy with at least 2 DMARDs taken continuously for at least 3 months each:

- azathioprine at a dose of at least 1 mg/kg per day; and/or
- cyclosporin at a dose of at least 2 mg/kg/day; and/or
- sodium aurothiomalate at a dose of 50 mg weekly.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances. Details of the toxicities, including severity, which will be accepted as a reason for substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial can be found on the Medicare Australia website [www.medicareaustralia.gov.au].

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance and dose for each DMARD must be provided in the authority application. Details of the toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy can be found on the Medicare Australia website [www.medicareaustralia.gov.au].

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

- an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either
  - (i) a total active joint count of at least 20 active (swollen and tender) joints; or
  - (ii) at least 4 active joints from the following list of major joints:
    - elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
    - shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website [www.medicareaustralia.gov.au]]; and
- (3) a signed patient acknowledgement.

A maximum of two infusions will be authorised under this restriction.

Assessment of a patient’s response to an initial course of treatment must be made at least 12 weeks after the first infusion so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia within 4 weeks of the date it was conducted. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with rituximab.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction.

Patients who fail to demonstrate a response to treatment with rituximab under this restriction will not be eligible to receive further PBS-subsidised
Where the most recent course of PBS-subsidised rituximab treatment was approved under either of the initial 1 or 2 treatment restrictions patients must be assessed for response at least 12 weeks after the first infusion. This assessment must be submitted to Medicare Australia no later than 4 weeks from the date of assessment.

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent provided they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The demonstration of response must be submitted to Medicare Australia within 4 weeks of assessment.

A patient whose most recent course of PBS-subsidised treatment with rituximab was approved under either of the initial 1 or 2 treatment restrictions patients must be assessed for response at least 12 weeks after the first infusion of their most recent treatment with rituximab. The demonstration of response must be submitted to Medicare Australia within 4 weeks of assessment.

Patients who fail to demonstrate a response to rituximab treatment and who qualify to trial an alternate bDMARD according to the interchangeability arrangements for bDMARDs for the treatment of severe rheumatoid arthritis, may do so without having to have a 22 week treatment-free period.

**Authority required**

Initial 2 (change or re-commencement after break of less than 24 months)

Initial course of PBS-subsidised treatment with rituximab, in combination with methotrexate at a dose of at least 7.5 mg weekly, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults who:

(a) have a documented history of severe active rheumatoid arthritis; and

(b) have failed to respond to at least 1 PBS-subsidised TNF-alfa antagonist; and

(c) have received prior PBS-subsidised bDMARD treatment for this condition and are eligible to receive further bDMARD therapy.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

Applications for patients who have received PBS-subsidised treatment with rituximab and who wish to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient’s most recent course of PBS-subsidised rituximab treatment, within the timeframes specified below.

A maximum of two infusions will be authorised under this restriction.

Where the most recent course of PBS-subsidised rituximab treatment was approved under either of the initial 1 or 2 treatment restrictions patients must be assessed for response at least 12 weeks after the first infusion. This assessment must be provided to Medicare Australia no later than 4 weeks from the date of assessment.

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent provided they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The demonstration of response must be submitted to Medicare Australia within 4 weeks of assessment.

A patient whose most recent course of PBS-subsidised treatment with rituximab was approved under either of the initial 1 or 2 treatment restrictions patients may do so without having to have a 22 week treatment-free period.

**Authority required**

Continuing treatment

Continuing PBS-subsidised treatment with rituximab, in combination with methotrexate at a dose of at least 7.5 mg weekly, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults:

(a) who have a documented history of severe active rheumatoid arthritis; and

(b) who have demonstrated an adequate response to treatment with rituximab; and

(c) whose most recent course of PBS-subsidised bDMARD treatment was with rituximab.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following:

(i) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(ii) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

- elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

- shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

A maximum of two infusions will be authorised under this restriction.

Patients may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The demonstration of response must be submitted to Medicare Australia within 4 weeks of assessment.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction.
Patients who fail to demonstrate a response to treatment with rituximab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**Note**

Any queries concerning the arrangements to prescribe rituximab may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Further prescribing information (including Authority Application Forms) is on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe rituximab should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

**Note**

TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying anti-rheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab) and the T-cell co-stimulation modulator (abatacept).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

PBS-subsidised abatacept, golimumab, infliximab and rituximab must be used in combination with methotrexate at a dose of at least 7.5 mg weekly. Where a patient cannot tolerate 7.5 mg of methotrexate weekly, they are eligible to receive PBS-subsidised adalimumab, certolizumab pegol, etanercept and tocilizumab.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:

- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact Medicare Australia on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent PBS-subsidised treatment was stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient wishes to commence treatment with a PBS-subsidised TNF-alfa antagonist after 1 August 2010, excluding rituximab (Initial 1); or

(ii) a patient wishes to re-commence treatment with a PBS-subsidised TNF-alfa antagonist after 1 August 2010, excluding rituximab (Initial 1); or

(iii) a patient wishes to re-commence treatment with a PBS-subsidised TNF-alfa antagonist after 1 August 2010, excluding rituximab (Initial 1); or

(iv) a patient wishes to re-commence treatment with a PBS-subsidised TNF-alfa antagonist after 1 August 2010, excluding rituximab (Initial 1); or

(b) Re-Commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab and tocilizumab, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to Medicare Australia within 4 weeks.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to...
For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:

Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:

A further application may be submitted to Medicare Australia 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept patients:

Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

Note

(3) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and Medicare Australia will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.
### HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

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**Note**
Special Pricing Arrangements apply.

#### THALIDOMIDE

**Authority required (STREAMLINED)**

3342
Multiple myeloma

**Caution**
Thalidomide is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and for 1 month after cessation of treatment.

**Note**
Patients receiving thalidomide under the PBS listing must be registered in the i-access risk management program.

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### MUSCULO-SKELETAL SYSTEM

#### MUSCLE RELAXANTS

**MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS**

*Other centrally acting agents*

**BACLOFEN**

*Authority required (STREAMLINED)*

- **3318**
  - Severe chronic spasticity, where oral antispastic agents have failed or have caused unacceptable side effects, in patients with chronic spasticity of cerebral origin.

*Authority required (STREAMLINED)*

- **3319**
  - Severe chronic spasticity, where oral antispastic agents have failed or have caused unacceptable side effects, in patients with chronic spasticity due to multiple sclerosis.

*Authority required (STREAMLINED)*

- **3320**
  - Severe chronic spasticity, where oral antispastic agents have failed or have caused unacceptable side effects, in patients with chronic spasticity due to spinal cord injury.

*Authority required (STREAMLINED)*

- **3321**
  - Severe chronic spasticity, where oral antispastic agents have failed or have caused unacceptable side effects, in patients with chronic spasticity due to spinal cord disease.

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#### DRUGS FOR TREATMENT OF BONE DISEASES

**DRUGS AFFECTING BONE STRUCTURE AND MINERALIZATION**

**Bisphosphonates**

**IBANDRONIC ACID**

*Authority required (STREAMLINED)*

- **3343**
  - Bone metastases from breast cancer.

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**PAMIDRONATE DISODIUM**

*Authority required (STREAMLINED)*

- **4433**
  - Hypercalcaemia of malignancy.

  **Clinical criteria:**
  - Patient must have a malignancy refractory to anti-neoplastic therapy.

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**PAMIDRONATE DISODIUM**

*Authority required (STREAMLINED)*

- **4425**
  - Hypercalcaemia of malignancy.

  **Clinical criteria:**
  - Patient must have a malignancy refractory to anti-neoplastic therapy.

  **Note**
  - Pharmaceutical benefits that have the form disodium pamidronate powder for I.V. infusion 30 mg (after reconstitution) and pharmaceutical benefits that have the form disodium pamidronate concentrated injection 30 mg are equivalent for the purposes of substitution.

<table>
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Amygdaloid cysts and muscle relaxation of the neck and shoulder muscles.
### PAMIDRONATE DISODIUM

**Authority required (STREAMLINED)**

**4421**

Hypercalcaemia of malignancy

**Authority required (STREAMLINED)**

**4432**

Multiple myeloma

**Authority required (STREAMLINED)**

**4426**

Bone metastases

**Clinical criteria:**

The condition must be due to breast cancer.

**Note**

Pharmaceutical benefits that have the form disodium pamidronate powder for I.V. infusion 90 mg (after reconstitution) and pharmaceutical benefits that have the form disodium pamidronate concentrated injection 90 mg are equivalent for the purposes of substitution.

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### ZOLEDRONIC ACID

**Authority required (STREAMLINED)**

**3342**

Multiple myeloma

**Authority required (STREAMLINED)**

**3343**

Bone metastases from breast cancer

**Authority required (STREAMLINED)**

**4052**

Bone metastases from castration-resistant prostate cancer

**Authority required (STREAMLINED)**

**3341**

Treatment of hypercalcaemia of malignancy refractory to anti-neoplastic therapy

**Note**

Special Pricing Arrangements apply.

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NERVOS SYSTEM

ANTI-PARKINSON DRUGS

DOPAMINERGIC AGENTS

Dopa and dopa derivatives

LEVODOPA + CARBIDOPA ANHYDROUS

Authority required (STREAMLINED)

3704

Management of advanced Parkinson disease in a patient with severe disabling motor fluctuations not adequately controlled by oral therapy.

Treatment must be commenced in a hospital-based movement disorder clinic

Note

Patients should have adequate cognitive function to manage administration with a portable continuous infusion pump.

A positive clinical response to Duodopa administered via a temporary nasoduodenal tube should be confirmed before a permanent percutaneous endoscopic gastrostomy (PEG) tube is inserted.

9743T

levodopa 20 mg/mL + carbidopa monohydrate 5 mg/mL gel: intestinal, 7 x 100 mL bags

8 5 .. 11536.00 Duodopa VE

Dopamine agonists

APOMORPHINE

Authority required (STREAMLINED)

3314

Parkinson’s disease in patients severely disabled by motor fluctuations which do not respond to other therapy

5609F

apomorphine hydrochloride 20 mg/2 mL injection, 5 x 2 mL ampoules

72 5 .. 7196.40 Apomine HH

5611H

apomorphine hydrochloride 50 mg/10 mL injection: subcutaneous infusion, 5 x 10 mL syringes

36 5 .. 7007.40 Apomine PFS HH

5610G

apomorphine hydrochloride 50 mg/5 mL injection, 5 x 5 mL ampoules

36 5 .. 9003.60 Apomine HH

PSYCHOLEPTICS

ANTIPSYCHOTICS

Diazepines, oxazepines, thiazepines and oxepines

CLOzapine

Authority required (STREAMLINED)

4411

Schizophrenia

Clinical criteria:

Patient must be non-responsive to other neuroleptic agents; OR

Patient must be intolerant of other neuroleptic agents.

A medical practitioner should request a quantity sufficient for up to one month’s supply. Up to 5 repeats will be authorised.

Note

Patients receiving clozapine under the PBS listing must be registered in a clozapine patient monitoring program: Novartis Clozaril Patient Monitoring System (CPMSplus) or Clopineconnect.

5629G

clozapine 100 mg tablet, 100

2 .. .. 281.66 Clopine 100 HH

5627F

clozapine 200 mg tablet, 100

2 .. .. 563.34 Clozaril 100 NV

5628F

clozapine 25 mg tablet, 100

2 .. .. 75.12 Clopine 25 HH

5626D

clozapine 50 mg tablet, 100

2 .. .. 150.24 Clozaril 25 NV

5630H

clozapine 50 mg/mL oral liquid, 100 mL

1 .. .. 135.00 Clopine Suspension HH
RESPIRATORY SYSTEM

DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES

OTHER SYSTEMIC DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES

OMALIZUMAB

Authority required

Initial treatment of uncontrolled severe allergic asthma

Initial PBS-subsidised treatment with omalizumab by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma, of a patient aged 12 years or older with uncontrolled severe allergic asthma who has been under the care of this physician for at least 12 months, and satisfies the following criteria:

(a) has a diagnosis of asthma confirmed and documented by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma, defined by standard clinical features, including:

(i) forced expiratory volume (FEV1) reversibility greater than or equal to 12% and greater than or equal to 200 mL at baseline within 30 minutes after administration of salbutamol (200 to 400 micrograms), or

(ii) airway hyperresponsiveness defined as a greater than 20% decline in FEV1 during a direct bronchial provocation test or greater than 15% decline during an indirect bronchial provocation test, or

(iii) peak expiratory flow (PEF) variability of greater than 15% between the two highest and two lowest peak expiratory flow rates during 14 days; and

(b) duration of asthma of at least 1 year; and

c) FEV1 less than or equal to 80% predicted, documented on 3 or more occasions in the previous 12 months; and

d) past or current evidence of atopy, documented by skin prick testing or RAST; and

e) total serum human immunoglobulin E (IgE) greater than or equal to 76 IU/mL; and

(f) has signed a patient acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criteria for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and

g) has failed to achieve adequate control with optimised asthma therapy, despite formal assessment of and adherence to correct inhaler technique, which has been documented (see NOTE). Optimised asthma therapy includes:

(i) adherence to maximal inhaled therapy, including high dose inhaled corticosteroid (budesonide 1600 micrograms per day or fluticasone propionate 1000 micrograms per day or equivalent), plus long-acting beta-2 agonist therapy (at least salmeterol 50 micrograms bd or eformoterol 12 micrograms bd) for at least 12 months, unless contraindicated or not tolerated, AND

(ii) oral corticosteroids (at least 10 mg per day prednisolone (or equivalent)) for at least 6 weeks, unless contraindicated or not tolerated.

If the requirement for treatment with optimised asthma therapy cannot be met because of contraindications according to the relevant TGA-approved Product Information and/or tolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the authority application. Details of the accepted toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement of treatment with optimised asthma therapy can be found on the Medicare Australia website [www.medicareaustralia.gov.au].

The initial IgE assessment must be no more than 12 months old at the time of application. A re-assessment of free IgE can only be made at least 12 months after the last dose of omalizumab. For patients re-commencing omalizumab within 12 months of the last dose the previous pre-omalizumab IgE level should be used.

The IgE pathology report must be provided with the authority application.

The following initiation criteria indicate failure to achieve adequate control and must be demonstrated in all patients at the time of the application:

(a) an Asthma Control Questionnaire (ACQ-5) score of at least 2.0, as assessed in the previous month, AND

(b) while on oral corticosteroids and in the past 12 months, experienced at least 1 admission to hospital for a severe asthma exacerbation, OR 1 severe asthma exacerbation, requiring documented use of systemic corticosteroids (oral corticosteroids initiated or increased for at least 3 days, or parental corticosteroids) prescribed/supervised by a physician.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Allergic Asthma PBS Authority Application - Supporting Information Form (may be downloaded from the Medicare Australia website [www.medicareaustralia.gov.au]) which includes the following:

(i) details of prior optimised asthma drug therapy (dosage, date of commencement and duration of therapy); and

(ii) details of severe exacerbation/s experienced while on oral corticosteroids (date and treatment); and

(iii) the signed patient acknowledgement; and

(c) a completed Asthma Control Questionnaire (ACQ-5) calculation sheet including the date of assessment of the patient's symptoms. (For copies of the ACQ please contact Novartis Medical Information on 1800 671 203 or medinfo.phauno@novartis.com)

At the time of the authority application, medical practitioners should request the appropriate maximum quantity and number of repeats to provide for an initial course of omalizumab consisting of the recommended number of doses for the baseline IgE level and body weight of the patient (refer
Where fewer than the required number of repeats to complete 28 weeks of treatment are requested at the time of the application, authority approvals for sufficient repeats to complete 28 weeks of omalizumab therapy may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period beyond 28 weeks.

The Asthma Control Questionnaire (5 item version) assessment of the patient’s response to this initial course of treatment, and the assessment of oral corticosteroid dose, must be made at around 24 to 26 weeks after the first dose so that there is adequate time for a response to be demonstrated and for the application for continuing therapy to be processed.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia within 4 weeks of the date of assessment, and no later than 2 weeks prior to the patient completing their current treatment course, to avoid an interruption to supply. Where a response assessment is not undertaken and submitted to Medicare Australia within this timeframe, the patient will be deemed to have failed to respond to treatment with omalizumab. It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 24 to 26 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised omalizumab treatment.

A patient who fails to respond to a course of PBS-subsidised omalizumab for the treatment of uncontrolled severe allergic asthma will not be eligible to receive further PBS-subsidised treatment with omalizumab for this condition within 6 months of the date on which treatment was ceased.

**Authority required**

Continuing treatment

Continuing PBS-subsidised treatment with omalizumab, by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma, of a patient who:

(a) has a documented history of severe allergic asthma; and

(b) has demonstrated or sustained an adequate response to treatment with omalizumab.

An adequate response to omalizumab treatment is defined as:

(a) a reduction in the Asthma Control Questionnaire (ACQ-5) score of at least 0.5 from baseline, OR

(b) maintenance oral corticosteroid dose reduced by at least 25% from baseline, and no deterioration in ACQ-5 score from baseline.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Allergic Asthma PBS Authority Application - Supporting Information Form (may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)) which includes details of maintenance oral corticosteroid dose; and

(c) a completed Asthma Control Questionnaire (ACQ-5) calculation sheet including the date of assessment of the patient’s symptoms. (For copies of the ACQ please contact Novartis Medical Information on 1800 671 203 or medinfo.phauno@novartis.com)

All applications for continuing treatment with omalizumab must include a measurement of response to the prior course of therapy. The Asthma Control Questionnaire (5 item version) assessment of the patient’s response to the prior course of treatment, and the assessment of oral corticosteroid dose, must be made at around 20 to 22 weeks after the first dose so that there is adequate time for a response to be demonstrated and for the application for continuing therapy to be processed.

The first assessment should, where possible, be completed by the same physician who initiated treatment with omalizumab. If the same physician cannot assess the patient please call Medicare Australia on 1800 700 270.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia within 4 weeks of the date of assessment, and no later than 2 weeks prior to the patient completing their current treatment course, to avoid an interruption to supply. Where a response assessment is not undertaken and submitted to Medicare Australia within this timeframe, the patient will be deemed to have failed to respond to treatment with omalizumab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 20 to 22 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised omalizumab treatment.

Patients are eligible to receive continuing courses of omalizumab treatment of up to 24 weeks providing they continue to demonstrate an adequate response to treatment.

At the time of the authority application, medical practitioners should request the appropriate maximum quantity and number of repeats to provide for a continuing course of omalizumab consisting of the recommended number of doses for the baseline IgE level and body weight of the patient (refer to the TGA-approved Product Information), sufficient for 24 weeks of therapy.

Where fewer than the required number of repeats to complete 24 weeks of treatment are requested at the time of the application, authority approvals for sufficient repeats to complete 24 weeks of omalizumab therapy may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

A patient who fails to respond to a course of PBS-subsidised omalizumab for the treatment of uncontrolled severe allergic asthma will not be eligible to receive further PBS-subsidised treatment with omalizumab for this condition within 6 months of the date on which treatment was ceased.

**Authority required**

**Initial PBS-subsidised treatment of severe allergic asthma in a patient who has previously received non-PBS-subsidised therapy with omalizumab (grandfather patients)**

Initial PBS-subsidised supply for continuing treatment with omalizumab by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma, of a patient aged 12 years or older with severe allergic asthma who satisfies the following criteria:

(a) has a diagnosis of asthma confirmed and documented by a respiratory physician, clinical immunologist, allergist or general physician.
experienced in the management of patients with severe asthma, defined by standard clinical features, including:

(i) forced expiratory volume (FEV1) reversibility greater than or equal to 12% and greater than or equal to 200 mL at baseline within 30 minutes after administration of salbutamol (200 to 400 micrograms), or

(ii) airway hyperresponsiveness defined as a greater than 20% decline in FEV1 during a direct bronchial provocation test or greater than 15% decline during an indirect bronchial provocation test, or

(iii) peak expiratory flow (PEF) variability of greater than 15% between the two highest and two lowest peak expiratory flow rates during 14 days; and

(b) duration of asthma of at least 1 year; and

(c) past or current evidence of atopy, documented by skin prick testing or RAST; and

(d) has signed a patient acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criteria for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment for grandfathered patients; and

(e) prior to omalizumab therapy had failed to achieve adequate control with optimised asthma therapy. Optimised asthma therapy includes:

(i) adherence to maximal inhaled therapy, including high dose inhaled corticosteroid (budesonide 1600 micrograms per day or fluticasone propionate 1000 micrograms per day or equivalent), plus long-acting beta-2 agonist therapy (at least salmeterol 50 micrograms bd or eformoterol 12 micrograms bd) for at least 12 months, and

(ii) may have included maintenance dose oral corticosteroids; and

(f) has demonstrated an adequate response to treatment with omalizumab.

A review of the patient’s records should be conducted to extract pre- and post-omalizumab data on symptoms, quality of life, medication doses, exacerbations and hospitalisations. Examples of parameters to establish response include:

(i) a reduction in Asthma Control Questionnaire (ACQ-5) score of at least 0.5;

(ii) an improvement of at least 0.5 in the Asthma Quality of Life Questionnaire (AQLQ or mini-AQLQ);

(iii) maintenance oral corticosteroid dose reduced by at least 25% from baseline; and/or

(iv) a reduction in the number of hospitalisations or severe exacerbations requiring use of systemic corticosteroids, compared to the 12 months prior to commencement of omalizumab.

Where baseline assessments are not available, please call Medicare Australia on 1800 700 270 to discuss.

If the requirement for treatment with optimised asthma therapy cannot be met because of contraindications according to the relevant TGA-approved Product Information and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the authority application. Details of the accepted contraindications and toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement of treatment with optimised asthma therapy can be found on the Medicare Australia website [www.medicareaustralia.gov.au].

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Allergic Asthma PBS Authority Application - Supporting Information Form (may be downloaded from the Medicare Australia website [www.medicareaustralia.gov.au]) which includes the following:

(i) details of prior optimised asthma drug therapy (dosage, date of commencement and duration of therapy); and

(ii) details of pre- and post-omalizumab data on symptoms, quality of life, medication doses, exacerbations and hospitalisations; and

(iii) the signed patient acknowledgement.

At the time of the authority application, medical practitioners should request the appropriate maximum quantity and number of repeats to provide for an initial course of omalizumab consisting of the recommended number of doses for the baseline IgE level and body weight of the patient (refer to the TGA-approved Product Information) to be administered every 2 or 4 weeks.

Where fewer than the required number of repeats to complete 24 weeks of treatment are requested at the time of the application, authority approvals for sufficient repeats to complete 24 weeks of omalizumab therapy may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period beyond 24 weeks.

An assessment of the patient’s continued response to this course of PBS-subsidised treatment must be made at around 20 to 22 weeks after the first dose so that there is adequate time for a response to be demonstrated and for the application for continuing therapy to be processed. The same parameters used to establish response to non-PBS-subsidised therapy with omalizumab should be used for the assessment.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia within 4 weeks of the date of assessment, and no later than 2 weeks prior to the patient completing their current treatment course, to avoid an interruption to supply. Where a response assessment is not undertaken and submitted to Medicare Australia within this timeframe, the patient will be deemed to have failed to respond to treatment with omalizumab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 20 to 22 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised omalizumab treatment.

Patients are eligible to receive continuing courses of omalizumab treatment of up to 24 weeks providing they continue to demonstrate an adequate response to treatment.

Patients may qualify for PBS-subsidised treatment under this restriction only. A patient who fails to respond to a course of PBS-subsidised omalizumab for the treatment of uncontrolled severe allergic asthma will not be eligible to receive further PBS-subsidised treatment with omalizumab for this condition within 6 months of the date on which treatment was ceased.
**TREATMENT OF ADULT AND ADOLESCENT PATIENTS WITH UNCONTROLLED SEVERE ALLERGIC ASTHMA**

Patients are eligible to commence an 'omalizumab treatment cycle' (initial treatment course with or without continuing treatment course/s) if they satisfy the eligibility criteria as detailed under the initial treatment restriction.

Once a patient has either failed to achieve or maintain a response to omalizumab, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 6 month break in PBS-subsidised omalizumab therapy before they are eligible to commence the next cycle. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised omalizumab treatment is stopped to the date of the first application for initial treatment with omalizumab under the new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

1. **How to prescribe PBS-subsidised omalizumab therapy.**

   **(a) Initial treatment.**

   Applications for initial treatment should be made where a patient has received no prior PBS-subsidised omalizumab treatment in this treatment cycle and wishes to commence such therapy.

   Initial treatment authorisations will be limited to provide for a maximum of 28 weeks of therapy with omalizumab. A patient must be assessed for response to a course of Initial PBS-subsidised treatment following a minimum of 24 weeks of therapy with omalizumab, and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date of assessment.

   Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with omalizumab.

   For second and subsequent courses of PBS-subsidised omalizumab treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

   **(b) Continuing treatment.**

   Following the completion of the initial treatment course with omalizumab, a patient may qualify to receive up to a further 24 weeks of continuing treatment with omalizumab providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing omalizumab treatment in courses of up to 24 weeks providing they continue to sustain the response.

   It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted omalizumab supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia within 4 weeks of the date of assessment, and no later than 2 weeks prior to the patient completing their current treatment course, to avoid an interruption to supply. Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with omalizumab.

2. **Baseline measurements to determine response.**

   Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) and oral corticosteroid dose, submitted with the Initial authority application for omalizumab. However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and Medicare Australia will assess response according to these revised baseline measurements.

3. **Re-commencement of treatment after a 6 month break in PBS-subsidised therapy.**

   A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised omalizumab therapy of at least 6 months, must re-qualify for initial treatment with respect to the indices of disease severity (oral corticosteroid dose, Asthma Control Questionnaire (ACQ-5) score, and relevant exacerbation history). Patients must have received optimised standard therapy, at adequate doses and for the minimum period specified, immediately prior to the time the new baseline assessments are performed.

4. **Patients ‘grandfathered’ onto PBS-subsidised treatment with omalizumab.**

   A patient who commenced treatment with omalizumab for uncontrolled severe allergic asthma prior to 1 November 2010 and who continues to receive treatment at the time of application, may qualify for treatment under the Initial ‘grandfather’ treatment restriction.

   A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with omalizumab will be authorised under this criterion.

   Following completion of the Initial PBS-subsidised course, further applications for treatment with omalizumab will be assessed under the continuing treatment restriction.
### HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

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#### COUGH AND COLD PREPARATIONS

**EXPECTORANTS, EXCL. COMBINATIONS WITH COUGH SUPPRESSANTS**

**Mucolytics**

**DORNASE ALFA**

**Authority required (STREAMLINED)**

4288

Cystic fibrosis

**Clinical criteria:**

- Patient must have a forced vital capacity (FVC) greater than 40% predicted for age, gender and weight.

AND

- Patient must have evidence of chronic suppurrative lung disease (cough and sputum most days of the week, or greater than 3 respiratory tract infections of more than 2 weeks' duration in any 12 months, or objective evidence of obstructive airways disease).

**Population criteria:**

- Patient must be 5 years of age or older.

- Patient must be assessed at a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis. The prescribing of dornase alfa therapy under the HSD program is limited to such physicians. If attendance at such a unit is not possible because of geographical isolation, management (including prescribing) may be by a specialist physician or paediatrician in consultation with such a unit.

- The measurement of lung function is to be conducted by independent (other than the treating doctor) experienced personnel at an established lung function testing laboratory, unless this is not possible because of geographical isolation.

Prior to dornase alfa therapy, a baseline measurement of forced expiratory volume in 1 second (FEV1) must be undertaken during a stable period of the disease.

Initial therapy is limited to 3 months treatment with dornase alfa at a dose of 2.5 mg daily.

FEV1 measurement (single test under conditions as above) and a global assessment of the patient involving the patient, the patient’s family (in the case of paediatric patients), the treating physician(s) and an additional independent member of the cystic fibrosis treatment team must be undertaken and documented following 3 months of initial therapy.

To be eligible for continued PBS-subsidised treatment with dornase alfa following 3 months of initial treatment:

1. The patient must demonstrate no deterioration in FEV1 compared to baseline; AND
2. The patient or the patient’s family (in the case of paediatric patients) must report improvement in the patient’s airway clearance; AND
3. The treating physician(s) must report a benefit in the clinical status of the patient.

Further reassessments involving the patient, the patient’s family (in the case of paediatric patients), the treating physician(s) and an additional independent member of the cystic fibrosis treatment team must be undertaken and documented at six-monthly intervals to establish that all agree that dornase alfa treatment is continuing to produce worthwhile benefits. Dornase alfa therapy should cease if there is not general agreement of benefit as there is always the possibility of harm from unnecessary use.

Other aspects of treatment, such as physiotherapy, must be continued.

Where there is documented evidence that a patient already receiving dornase alfa therapy would have met the criteria for subsidy, then the patient...
is eligible to continue treatment under the HSD program. Where such evidence is not available, patients will need to satisfy the initiation and continuation criteria as for new patients. (Four weeks is considered a suitable wash-out period.)

**Authority required (STREAMLINED)**

4300
Cystic fibrosis

**Clinical criteria:**

Patient must have a severe clinical course with frequent respiratory exacerbations or chronic respiratory symptoms (including chronic or recurrent cough, wheeze or tachypnoea) requiring hospital admissions more frequently than 3 times per year; OR

Patient must have significant bronchiectasis on chest high resolution computed tomography scan; OR

Patient must have severe cystic fibrosis bronchiolitis with persistent wheeze non-responsive to conventional medicines; OR

Patient must have severe physiological deficit measure by forced oscillation technique or multiple breath nitrogen washout and failure to respond to traditional therapy.

**Population criteria:**

Patient must be less than 5 years of age.

Patient must be assessed at a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis. The prescribing of dornase alfa therapy under the HSD program is limited to such physicians. If attendance at such a unit is not possible because of geographical isolation, management (including prescribing) may be by a specialist physician or paediatrician in consultation with such a unit.

Following an initial 6 months therapy, a comprehensive assessment must be undertaken and documented involving the patient, the patient’s family, the treating physician and an additional independent member of the cystic fibrosis treatment team to establish agreement that dornase alfa treatment is continuing to produce worthwhile benefit. Treatment with dornase alfa should cease if there is not agreement of benefit, as there is always the possibility of harm from unnecessary use. Further reassessments must be undertaken and documented at six-monthly intervals.

**Authority required (STREAMLINED)**

4296
Cystic fibrosis

**Treatment Phase: Continuing treatment**

**Clinical criteria:**

Patient must have initiated treatment with dornase alfa at an age of less than 5 years, AND

Patient must have undergone a comprehensive assessment, involving the patient’s family, the treating physician and an additional independent member of the cystic fibrosis treatment team which documents agreement that dornase alfa treatment is continuing to produce worthwhile benefit.

**Population criteria:**

Patient must be 5 years of age or older.

Further reassessments must be undertaken and documented at six-monthly intervals. Treatment with dornase alfa should cease if there is not agreement of benefit as there is always the possibility of harm from unnecessary use.

**Authority required (STREAMLINED)**

4298
Cystic fibrosis

**Clinical criteria:**

Patient must have initiated treatment with dornase alfa prior to 1 November 2009, AND

Patient must have undergone a comprehensive assessment, involving the patient’s family, the treating physician and an additional independent member of the cystic fibrosis treatment team which documents agreement that dornase alfa treatment is continuing to produce worthwhile benefit.

**Population criteria:**

Patient must be less than 5 years of age.

Further reassessments must be undertaken and documented at six-monthly intervals. Treatment with dornase alfa should cease if there is not agreement of benefit as there is always the possibility of harm from unnecessary use.

**Note**

Dornase alfa is not PBS-subsidised for use in combination with PBS-subsidised mannitol.

**Note**

It is highly desirable that all patients be included in the national cystic fibrosis patient database.

**Brand Name and Manufacturer**

Pulmozyme

**Price for Max. Qty $**

\*2360.00

**Dispensed**

5704F
dornase alfa 2.5 mg/2.5 mL inhalation: solution, 30 x 2.5 mL ampoules

**Authority required (STREAMLINED)**
HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>Qty $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>4299</td>
<td>Cystic fibrosis</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Clinical criteria:**

Patient must have been assessed for bronchial hyperresponsiveness as per the TGA approved Product Information mannitol initiation dose assessment, prior to mannitol therapy. If the patient has a negative hyperresponsiveness test they may be eligible for PBS subsidised treatment with mannitol,

**AND**

Patient must have a forced expiratory volume in 1 second (FEV1) greater than 30% predicted for age, gender and height,

**AND**

Patient must be intolerant or inadequately responsive to dornase alfa,

**AND**

Patient must have evidence of chronic suppurative lung disease (cough and sputum most days of the week, or greater than 3 respiratory tract infections of more than 2 weeks’ duration in any 12 months, or objective evidence of obstructive airways disease).

**Population criteria:**

Patient must be 6 years of age or older.

Patient must be assessed at a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis. The prescribing of mannitol therapy under the HSD program is limited to such physicians. If attendance at such a unit is not possible because of geographical isolation, management (including prescribing) may be by a specialist physician or paediatrician in consultation with such a unit.

The measurement of lung function is to be conducted by independent (other than the treating doctor) experienced personnel at an established lung function testing laboratory, unless this is not possible because of geographical isolation.

Prior to mannitol therapy, a baseline measurement of FEV1 must be undertaken during a stable period of the disease.

Initial therapy is limited to 3 months treatment with mannitol at a dose of 400 mg twice daily.

FEV1 measurement (single test under conditions as above) and a global assessment of the patient involving the patient, the patient’s family (in the case of paediatric patients), the treating physician(s) and an additional independent member of the cystic fibrosis treatment team must be undertaken and documented following 3 months of initial therapy.

To be eligible for continued PBS-subsidised treatment with mannitol following 3 months of initial treatment:

1. the patient must demonstrate no deterioration in FEV1 compared to baseline; AND
2. the patient or the patient’s family (in the case of paediatric patients) must report improvement in the patient’s airway clearance; AND
3. the treating physician(s) must report a benefit in the clinical status of the patient.

Further reassessments involving the patient, the patient’s family (in the case of paediatric patients), the treating physician(s) and an additional independent member of the cystic fibrosis treatment team must be undertaken and documented at six-monthly intervals to establish that all agree that mannitol treatment is continuing to produce worthwhile benefits. Mannitol therapy should cease if there is not general agreement of benefit as there is always the possibility of harm from unnecessary use.

Other aspects of treatment, such as physiotherapy, must be continued.

Where there is documented evidence that a patient already receiving mannitol therapy would have met the criteria for subsidy then the patient is eligible to continue treatment under the HSD program. Where such evidence is not available, patients will need to satisfy the initiation and continuation criteria as for new patients. (Four weeks is considered a suitable wash-out period.)

**Authority required (STREAMLINED)**

<table>
<thead>
<tr>
<th>Code</th>
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<th>No. of Rpts</th>
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<tbody>
<tr>
<td>4293</td>
<td>Cystic fibrosis</td>
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</table>

**Clinical criteria:**

Patient must have initiated treatment with mannitol prior to 1 August 2012,

**AND**

Patient must have undergone a comprehensive assessment involving the patient’s family, the treating physician and an additional independent member of the cystic fibrosis team, which documents agreement that mannitol treatment is continuing to produce a worthwhile benefit.

**Population criteria:**

Patient must be 6 years of age or older.

Further reassessments are to be undertaken and documented every 6 months. Treatment with mannitol should cease if there is not agreement of benefit as there is always the possibility of harm from unnecessary use.

**Note**

Mannitol is not PBS-subsidised for use in combination with PBS-subsidised dornase alfa.

**Note**

It is highly desirable that all patients be included in the national cystic fibrosis patient database.

<table>
<thead>
<tr>
<th>Code</th>
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<th>Premium $</th>
<th>Qty $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>2015C</td>
<td>MANNITOL Pack containing 280 capsules containing powder for inhalation 40 mg and 2 inhalers, 1</td>
<td>4</td>
<td>5</td>
<td>..</td>
<td>1736.00</td>
<td>bronchitol XA</td>
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</table>
### ALL OTHER THERAPEUTIC PRODUCTS

#### Iron chelating agents

**DEFERASIROX**  
*Authority required (STREAMLINED)*  
3828  
Chronic iron overload in patients with disorders of erythropoiesis  

**Note**  
Special Pricing Arrangements apply.

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
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<th>Dispensed Price for Max. Qty $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>5654N</td>
<td>deferasirox 125 mg tablet: dispersible, 28</td>
<td>6</td>
<td>5</td>
<td>..</td>
<td>*1401.48</td>
<td>Exjade NV</td>
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<tr>
<td>5655P</td>
<td>deferasirox 250 mg tablet: dispersible, 28</td>
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<td>5</td>
<td>..</td>
<td>*2802.90</td>
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<td>5656Q</td>
<td>deferasirox 500 mg tablet: dispersible, 28</td>
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<td>5</td>
<td>..</td>
<td>*5605.80</td>
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</table>

**DEFERIPRONE**  
*Authority required (STREAMLINED)*  
3338  
Iron overload in patients with thalassaemia major who are unable to take desferrioxamine therapy  

**Note**  
Special Pricing Arrangements apply.

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
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<th>Brand Name and Manufacturer</th>
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<tr>
<td>5658T</td>
<td>deferiprone 100 mg/mL oral liquid, 250 mL</td>
<td>5</td>
<td>5</td>
<td>..</td>
<td>*1126.40</td>
<td>Ferriprox OA</td>
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<tr>
<td>5657R</td>
<td>deferiprone 500 mg tablet, 100</td>
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<td>5</td>
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<td>*2703.36</td>
<td>Ferriprox OA</td>
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**DESFERRIOXAMINE**  
*Authority required (STREAMLINED)*  
3340  
Disorders of erythropoiesis associated with treatment-related chronic iron overload  

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
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<th>No. of Rpts</th>
<th>Premium $</th>
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<tr>
<td>5661Y</td>
<td>desferrioxamine mesylate 2 g injection, 1 x 2 g vial</td>
<td>60</td>
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<td>*1944.00</td>
<td>Hospira Pty Limited HH</td>
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<td>5662B</td>
<td>desferrioxamine mesylate 500 mg injection, 10 x 500</td>
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<td>5</td>
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</table>

**Drugs for treatment of hyperkalemia and hyperphosphatemia**

**LANTHANUM**  
*Authority required (STREAMLINED)*  
3390  
Management of hyperphosphataemia in a patient with chronic kidney disease on dialysis whose serum phosphate is not controlled on calcium and where serum phosphate is greater than 1.6 mmol per L at the commencement of therapy.  

Management includes initiation, stabilisation and review of therapy as required  

**Authority required (STREAMLINED)**  
3391  
Management of hyperphosphataemia in a patient with chronic kidney disease on dialysis whose serum phosphate is not controlled on calcium and where the serum calcium times phosphate product is greater than 4.0 at the commencement of therapy.  

Management includes initiation, stabilisation and review of therapy as required  

**Note**  
Not to be used in combination with sevelamer.

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>Dispensed Price for Max. Qty $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>5782H</td>
<td>LANTHANUM Tablet, chewable, 1000 mg (as carbonate hydrate), 90</td>
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<td>5</td>
<td>..</td>
<td>*890.02</td>
<td>Fosrenol ZI</td>
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<tr>
<td>5780F</td>
<td>LANTHANUM Tablet, chewable, 500 mg (as carbonate hydrate), 90</td>
<td>2</td>
<td>5</td>
<td>..</td>
<td>*523.54</td>
<td>Fosrenol ZI</td>
</tr>
<tr>
<td>Code</td>
<td>Name, Restriction, Manner of Administration and Form</td>
<td>Max. Qty (Packs)</td>
<td>No. of Rpts</td>
<td>Premium Qty $</td>
<td>Dispensed Price for Max. Qty $</td>
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<tr>
<td>5781G</td>
<td>LANTHANUM Tablet, chewable, 750 mg (as carbonate hydrate), 90</td>
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<td>5</td>
<td>..</td>
<td>*790.56</td>
<td>Fosrenol</td>
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</table>

SEVELAMER

**Authority required (STREAMLINED)**

3390

Management of hyperphosphataemia in a patient with chronic kidney disease on dialysis whose serum phosphate is not controlled on calcium and where serum phosphate is greater than 1.6 mmol per L at the commencement of therapy.

Management includes initiation, stabilisation and review of therapy as required

**Authority required (STREAMLINED)**

3391

Management of hyperphosphataemia in a patient with chronic kidney disease on dialysis whose serum phosphate is not controlled on calcium and where the serum calcium times phosphate product is greater than 4.0 at the commencement of therapy.

Management includes initiation, stabilisation and review of therapy as required

**Note**

Not to be used in combination with lanthanum.

9546K  | sevelamer hydrochloride 800 mg tablet, 180 | 2               | 5           | ..            | *620.00                      | Renagel                    |
SECTION 100 (BOTULINUM TOXIN PROGRAM)

BOTULINUM TOXIN TYPE A

Criteria for availability
Blepharospasm or hemifacial spasm

Population criteria:
Patient must be aged 12 years or older.

Note
Arrangements to prescribe this item should be made by medical practitioners with the Department of Human Services, contact telephone number 1800 700 270.

Note
The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent.

Criteria for availability
Dynamic equinus foot deformity

Clinical criteria:
The condition must be due to spasticity,

AND
Patient must be an ambulant cerebral palsy patient.

Population criteria:
Patient must be aged from 2 to 17 years inclusive.

Note
Arrangements to prescribe this item should be made by medical practitioners with the Department of Human Services, contact telephone number 1800 700 270.

Note
The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent.

Criteria for availability
Dynamic equinus foot deformity

Clinical criteria:
The condition must be due to spasticity,

AND
Patient must be an ambulant cerebral palsy patient,

AND
Patient must have commenced on PBS-subsidised treatment with botulinum toxin type A purified neurotoxin complex as a paediatric patient.

Population criteria:
Patient must be aged 18 years or older.

Note
Arrangements to prescribe this item should be made by medical practitioners with the Department of Human Services, contact telephone number 1800 700 270.

Note
The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent.

Criteria for availability
Spasmodic torticollis

Clinical criteria:
The treatment must be as monotherapy; OR
The treatment must be as adjunctive therapy to current standard care.

Note
Arrangements to prescribe this item should be made by medical practitioners with the Department of Human Services, contact telephone number 1800 700 270.

Note
The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent.

Criteria for availability
Moderate to severe spasticity of the upper limb

Clinical criteria:
Patient must have cerebral palsy.

Population criteria:
Patient must be aged from 2 to 17 years inclusive.

Note
### SECTION 100 (BOTULINUM TOXIN PROGRAM)

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>Price ex manufacturer $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td></td>
<td>Arrangements to prescribe this item should be made by medical practitioners with the Department of Human Services, contact telephone number 1800 700 270.</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Note**
The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent.

**Criteria for availability**
Moderate to severe spasticity of the upper limb

**Clinical criteria:**
Patient must have cerebral palsy.

AND
Patient must have commenced on PBS-subsidised treatment with botulinum toxin type A purified neurotoxin complex as a paediatric patient.

**Population criteria:**
Patient must be aged 18 years or older.

**Note**
Arrangements to prescribe this item should be made by medical practitioners with the Department of Human Services, contact telephone number 1800 700 270.

**Note**
Contact the Department of Human Services before commencing PBS-subsidised treatment in cerebral palsy patients who have been treated for moderate to severe spasticity of the upper limb with non-PBS-subsidised botulinum toxin prior to the age of 18.

**Note**
The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent.

**Criteria for availability**
Moderate to severe spasticity of the upper limb following a stroke

**Clinical criteria:**
The treatment must be used as second line therapy when standard management has failed (e.g. physiotherapy and/or oral spasticity agents) or as an adjunct to physical therapy.

**Population criteria:**
Patient must be an adult.

Moderate to severe spasticity is defined as MAS greater than or equal to 3 using modified Ashworth scale.

Maximum number of treatments to be authorised is 4 (total Botox and Dysport) per upper limb per lifetime. Treatment should not be initiated until 3 months post-stroke in patients who do not have established severe contracture. Treatment should be discontinued if the patient does not respond (decrease of MAS greater than 1 in at least one joint) after two treatments.

The date of the stroke must be provided.

Contraindications to treatment include established severe contracture and known sensitivity to botulinum toxin.

**Note**
Arrangements to prescribe this item should be made by medical practitioners with the Department of Human Services, contact telephone number 1800 700 270.

**Note**
The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent.

**Criteria for availability**
Severe primary axillary hyperhidrosis

**Clinical criteria:**
Patient must have previously failed or be intolerant to topical aluminium chloride hexahydrate after one to two months of treatment.

**Population criteria:**
Patient must be aged 12 years or older.

Maximum number of treatments per year is 3, with no less than 4 months to elapse between treatments.

**Note**
Arrangements to prescribe this item should be made by medical practitioners with the Department of Human Services, contact telephone number 1800 700 270.

**Note**
The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent.

**Note**
Special Pricing Arrangements apply.

**Criteria for availability**
Urinary incontinence

**Clinical criteria:**
The condition must be due to neurogenic detrusor overactivity, as demonstrated by urodynamic study,
SECTION 100 (BOTULINUM TOXIN PROGRAM)

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>Price ex manufacturer $</th>
<th>Brand Name and Manufacturer</th>
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<tr>
<td>6103F</td>
<td>botulinum toxin type A 100 units injection, 1 x 100 units vial</td>
<td>1</td>
<td>415.50</td>
<td>Botox AG</td>
</tr>
</tbody>
</table>

AND

The condition must be inadequately controlled by anti-cholinergic therapy,

AND

Patient must experience at least 14 episodes of urinary incontinence per week prior to commencement of treatment with botulinum toxin,

AND

The treatment must not continue if the patient does not achieve a 50% or greater reduction from baseline in urinary incontinence episodes 6-12 weeks after the first treatment,

AND

Patient must be willing and able to self-catheterise.

Population criteria:

Patient must have multiple sclerosis; OR

Patient must have a spinal cord injury; OR

Patient must be aged 18 years or older and have spina bifida.

Note

Arrangements to prescribe this item should be made by medical practitioners with the Department of Human Services, contact telephone number 1800 700 270.

Note

The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent.

Criteria for availability

Chronic migraine

Clinical criteria:

Patient must have experienced an average of 15 or more headache days per month, with at least 8 days of migraine, over a period of at least 6 months, prior to commencement of treatment with botulinum toxin,

AND

Patient must have experienced an inadequate response, intolerance or a contraindication to at least three prophylactic migraine medications prior to commencement of treatment with botulinum toxin,

AND

Patient must have achieved and maintained a 50% or greater reduction from baseline in the number of headache days per month after two treatment cycles (each of 12 weeks duration) in order to be eligible for continuing PBS-subsidised treatment.

Population criteria:

Patient must be an adult.

Medication overuse headache must be appropriately managed prior to initiation of treatment with botulinum toxin.

Note

Arrangements to prescribe this item should be made by medical practitioners with the Department of Human Services, contact telephone number 1800 700 270.

Note

The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent.

Criteria for availability

CLOSTRIDIUM BOTULINUM TYPE A TOXIN-HAEMAGGLUTININ COMPLEX

Criteria for availability

Treatment of dynamic equinus foot deformity due to spasticity in an ambulant paediatric cerebral palsy patient aged from 2 to 17 years inclusive

Criteria for availability

Continuing PBS-subsidised treatment of dynamic equinus foot deformity due to spasticity in an ambulant cerebral palsy patient 18 years of age or older who was commenced on PBS-subsidised treatment with clostridium botulinum type A toxin-haemagglutinin complex as a paediatric patient

Criteria for availability

Treatment of spasmodic torticollis, either as monotherapy or as adjunctive therapy to current standard care

Criteria for availability

Treatment of blepharospasm or hemifacial spasm in an adult

Criteria for availability

Treatment of moderate to severe spasticity [defined as MAS greater than or equal to 3 using modified Ashworth scale] of the upper limb in adults following a stroke, as second line therapy when standard management has failed (e.g. physiotherapy and/or oral spasticity agents) or as an
adjunct to physical therapy.

Maximum number of treatments to be authorised is 4 (total Botox and Dysport) per upper limb per lifetime. Treatment should not be initiated until 3 months post-stroke in patients who do not have established severe contracture. Treatment should be discontinued if the patient does not respond (decrease of MAS greater than 1 in at least one joint) after two treatments.

The date of the stroke must be provided.

Contraindications to treatment include established severe contracture and known sensitivity to botulinum toxin

**Note**
Arrangements to prescribe this item should be made by medical practitioners with Medicare Australia, contact telephone number 1800 700 270.

**Note**
The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent.

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty</th>
<th>Price ex manufacturer</th>
<th>Brand Name and Manufacturer</th>
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<tr>
<td>1152P</td>
<td>clostridium botulinum type A toxin-haemagglutinin complex 300 units injection, 1 x 300 units vial</td>
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<td>$361.52</td>
<td>Dysport IS</td>
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<tr>
<td>6293F</td>
<td>clostridium botulinum type A toxin-haemagglutinin complex 500 units injection, 1 x 500 units vial</td>
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<td>$644.81</td>
<td>Dysport IS</td>
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</tbody>
</table>
### SOMATROPIN

#### Criteria for availability

Short stature in accordance with the 'Guidelines for the Pharmaceutical Benefits Scheme Growth Hormone Program'. The program also aims to correct neonatal hypoglycaemia due to biochemical growth hormone deficiency and improve body composition for children with Prader-Willi Syndrome.

The Guidelines specify the eligibility criteria for the conditions that are eligible for treatment through the program which include:

(i) short stature and slow growth;
(ii) short stature associated with biochemical growth hormone deficiency;
(iii) growth retardation secondary to intracranial lesion or cranial irradiation;
(iv) neonates/infants at risk of hypoglycaemia secondary to growth hormone deficiency;
(v) short stature associated with Turner Syndrome;
(vi) short stature due to short stature homeobox (SHOX) gene disorders;
(vii) short stature associated with chronic renal insufficiency;
(viii) biochemical growth hormone deficiency and precocious puberty;
(ix) Prader-Willi syndrome.

Genotropin branded products are available for the treatment of Prader-Willi Syndrome in accordance with the Guidelines

#### Note

Growth hormone (Somatropin) for adults is currently not subsidised through the Pharmaceutical Benefits Scheme.

These guidelines may be obtained from the Department of Health and Ageing's internet site at [http://www.health.gov.au/hGH](http://www.health.gov.au/hGH), or from:

**Growth Hormone Program**

**Access and Systems Branch**

Department of Health and Ageing

GPO Box 9848

**CANBERRA ACT 2601**

Contact telephone number (02) 6289 7274

#### Table

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty</th>
<th>Price ex manufacturer</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>6329D</td>
<td>SOMATROPIN (Recombinant human growth hormone) Injection 8 mg (24 i.u.) vial with 1.37 mL diluent cartridge (with preservative) (for use with one.click auto-injector), 1</td>
<td>1</td>
<td>396.00</td>
<td>Saizen 8 mg click.easy SG</td>
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<tr>
<td>9586M</td>
<td>SOMATROPIN (Recombinant human growth hormone) Powder for injection 12 mg (36 i.u.) with diluent in pre-filled pen (with preservative), 1</td>
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<td>594.00</td>
<td>Genotropin GoQuick PF</td>
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<tr>
<td>9585L</td>
<td>SOMATROPIN (Recombinant human growth hormone) Powder for injection 5 mg (15 i.u.) with diluent in pre-filled pen (with preservative), 1</td>
<td>1</td>
<td>247.50</td>
<td>Genotropin GoQuick PF</td>
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<tr>
<td>9628R</td>
<td>somatropin 1.8 international units (600 microgram) injection [7 x 600 microgram syringes] (&amp;) inert substance diluent [7 x 0.25 mL syringes], 1 pack</td>
<td>1</td>
<td>207.90</td>
<td>Genotropin MiniQuick PF</td>
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<tr>
<td>6266T</td>
<td>somatropin 12 international units (4 mg) injection [1 x 4 mg vial] (&amp;) inert substance diluent [1 vial], 1 pack</td>
<td>1</td>
<td>198.00</td>
<td>Zomacton FP</td>
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<td>somatropin 15 international units (5 mg/1.5 mL) injection, 1 x 1.5 mL cartridge</td>
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<td>Norditropin SimpleX NO</td>
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<tr>
<td>6476W</td>
<td>somatropin 15 international units (5 mg/1.5 mL) injection, 1 x 1.5 mL cartridge</td>
<td>1</td>
<td>247.50</td>
<td>Omnitrope SZ</td>
</tr>
<tr>
<td>6169Q</td>
<td>somatropin 18 international units (6 mg) injection [1 x 6 mg cartridge] (&amp;) inert substance diluent [1 x 3.15 mL syringe], 1 pack</td>
<td>1</td>
<td>297.00</td>
<td>Humatrope LY</td>
</tr>
<tr>
<td>5822K</td>
<td>somatropin 18 international units (6 mg/1.03 mL) injection, 1 x 1.03 mL cartridge</td>
<td>1</td>
<td>297.00</td>
<td>Saizen SG</td>
</tr>
<tr>
<td>6313G</td>
<td>somatropin 2.4 international units (800 microgram) injection [7 x 800 microgram syringes] (&amp;) inert substance diluent [7 x 0.25 mL syringes], 1 pack</td>
<td>1</td>
<td>277.20</td>
<td>Genotropin MiniQuick PF</td>
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<tr>
<td>6314H</td>
<td>somatropin 3 international units (1 mg) injection [7 x 1 mg syringes] (&amp;) inert substance diluent [7 x 0.25 mL syringes], 1 pack</td>
<td>1</td>
<td>346.50</td>
<td>Genotropin MiniQuick PF</td>
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<tr>
<td>6315J</td>
<td>somatropin 3.6 international units (1.2 mg) injection [7 x 1.2 mg syringes] (&amp;) inert substance diluent [7 x 0.25 mL syringes], 1 pack</td>
<td>1</td>
<td>415.80</td>
<td>Genotropin MiniQuick PF</td>
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<tr>
<td>6310D</td>
<td>somatropin 30 international units (10 mg) injection [1 x 10 mg vial] (&amp;) inert substance diluent [1 x 1 mL syringe], 1 pack</td>
<td>1</td>
<td>495.00</td>
<td>Zomacton FP</td>
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<tr>
<td>6296J</td>
<td>somatropin 30 international units (10 mg/1.5 mL) injection, 1 x 1.5 mL cartridge</td>
<td>1</td>
<td>495.00</td>
<td>Norditropin SimpleX NO</td>
</tr>
<tr>
<td>6311E</td>
<td>somatropin 30 international units (10 mg/1.5 mL) injection, 1 x 1.5 mL cartridge</td>
<td>1</td>
<td>495.00</td>
<td>Omnitrope SZ</td>
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### SECTION 100 (HUMAN GROWTH HORMONE)

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<thead>
<tr>
<th>Code</th>
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<th>Price ex manufacturer</th>
<th>Brand Name and Manufacturer</th>
</tr>
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<tbody>
<tr>
<td>9604L</td>
<td>somatropin 30 international units (10 mg/2 mL) injection, 1 x 2 mL cartridge</td>
<td>1</td>
<td>495.00</td>
<td>NutropinAq IS</td>
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<tr>
<td>6312F</td>
<td>somatropin 36 international units (12 mg) injection [1 x 12 mg cartridge] (&amp;) inert substance diluent [1 x 1 mL cartridge], 1 pack</td>
<td>1</td>
<td>594.00</td>
<td>Genotropin PF</td>
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<tr>
<td>6170R</td>
<td>somatropin 36 international units (12 mg) injection [1 x 12 mg cartridge] (&amp;) inert substance diluent [1 x 3.15 mL syringe], 1 pack</td>
<td>1</td>
<td>594.00</td>
<td>Humatrope LY</td>
</tr>
<tr>
<td>5824M</td>
<td>somatropin 36 international units (12 mg/1.5 mL) injection, 1 x 1.5 mL cartridge</td>
<td>1</td>
<td>594.00</td>
<td>Saizen SG</td>
</tr>
<tr>
<td>6316K</td>
<td>somatropin 4.2 international units (1.4 mg) injection [7 x 1.4 mg syringes] (&amp;) inert substance diluent [7 x 0.25 mL syringes], 1 pack</td>
<td>1</td>
<td>485.10</td>
<td>Genotropin MiniQuick PF</td>
</tr>
<tr>
<td>6317L</td>
<td>somatropin 4.8 international units (1.6 mg) injection [7 x 1.6 mg syringes] (&amp;) inert substance diluent [7 x 0.25 mL syringes], 1 pack</td>
<td>1</td>
<td>554.40</td>
<td>Genotropin MiniQuick PF</td>
</tr>
<tr>
<td>6297K</td>
<td>somatropin 45 international units (15 mg/1.5 mL) injection, 1 x 1.5 mL cartridge</td>
<td>1</td>
<td>742.50</td>
<td>Norditropin SimpleXx NO</td>
</tr>
<tr>
<td>6318M</td>
<td>somatropin 5.4 international units (1.8 mg) injection [7 x 1.8 mg syringes] (&amp;) inert substance diluent [7 x 0.25 mL syringes], 1 pack</td>
<td>1</td>
<td>623.70</td>
<td>Genotropin MiniQuick PF</td>
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<tr>
<td>6319N</td>
<td>somatropin 6 international units (2 mg) injection [7 x 2 mg syringes] (&amp;) inert substance diluent [7 x 0.25 mL syringes], 1 pack</td>
<td>1</td>
<td>693.00</td>
<td>Genotropin MiniQuick PF</td>
</tr>
<tr>
<td>3388H</td>
<td>somatropin 60 international units (20 mg/2.5 mL) injection, 1 x 2.5 mL cartridge</td>
<td>1</td>
<td>990.00</td>
<td>Saizen SG</td>
</tr>
<tr>
<td>6345Y</td>
<td>somatropin 72 international units (24 mg) injection [1 x 24 mg cartridge] (&amp;) inert substance diluent [1 x 3.15 mL syringe], 1 pack</td>
<td>1</td>
<td>1188.00</td>
<td>Humatrope LY</td>
</tr>
</tbody>
</table>

**SOMATROPIN**

**Criteria for availability**

Short stature in accordance with the ‘Guidelines for the Pharmaceutical Benefits Scheme Growth Hormone Program. The program also aims to correct neonatal hypoglycaemia due to biochemical growth hormone deficiency and improve body composition for children with Prader-Willi Syndrome.

The Guidelines specify the eligibility criteria for the conditions that are eligible for treatment through the program which include:

(i) short stature and slow growth;
(ii) short stature associated with biochemical growth hormone deficiency;
(iii) growth retardation secondary to intracranial lesion or cranial irradiation;
(iv) neonates/infants at risk of hypoglycaemia secondary to growth hormone deficiency;
(v) short stature associated with Turner Syndrome;
(vi) short stature due to short stature homeobox (SHOX) gene disorders;
(vii) short stature associated with chronic renal insufficiency;
(viii) biochemical growth hormone deficiency and precocious puberty;
(ix) Prader-Willi syndrome.

Genotropin branded products are available for the treatment of Prader-Willi Syndrome in accordance with the Guidelines

**Note**

Growth hormone (Somatropin) for adults is currently not subsidised through the Pharmaceutical Benefits Scheme.

These guidelines may be obtained from the Department of Health and Ageing’s internet site at http://www.health.gov.au/hGH, or from:

Growth Hormone Program
Access and Systems Branch
Department of Health and Ageing
GPO Box 9848
CANBERRA ACT 2601
Contact telephone number (02) 6289 7274

**Note**

Special Pricing Arrangements apply.
### SECTION 100 (IVF/GIFT TREATMENT)

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty</th>
<th>Price ex manufacturer $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>CETRORELIX</td>
<td><strong>Criteria for availability</strong>&lt;br&gt;For the prevention of premature luteinisation and ovulation in patients undergoing controlled ovarian stimulation, followed by oocyte pick-up and assisted reproductive techniques as described in items 13200, 13201, 13202 or 13203 of the Medicare Benefits Schedule</td>
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<td></td>
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<tr>
<td>9599F</td>
<td>cetrorelix 250 microgram injection [1 x 250 microgram vial] [&amp;] inert substance diluent [1 x 1 mL syringe], 1 pack</td>
<td>1</td>
<td>46.08</td>
<td>Cetrotide SG</td>
</tr>
<tr>
<td>CHORIOGONADOTROPIN ALFA</td>
<td><strong>Criteria for availability</strong>&lt;br&gt;Patients who are receiving medical treatment as described in items 13200, 13201, 13202 or 13203 of the Medicare Benefits Schedule</td>
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</tr>
<tr>
<td>6182J</td>
<td>choriogonadotropin alfa 250 microgram/0.5 mL injection, 1 x 0.5 mL cartridge</td>
<td>1</td>
<td>54.80</td>
<td>Ovidrel SG</td>
</tr>
<tr>
<td>9631X</td>
<td>choriogonadotropin alfa 250 microgram/0.5 mL injection, 1 x 0.5 mL syringe</td>
<td>1</td>
<td>54.80</td>
<td>Ovidrel SG</td>
</tr>
<tr>
<td>CORIFOLLITROPIN ALFA</td>
<td><strong>Criteria for availability</strong>&lt;br&gt;Controlled ovarian stimulation&lt;br&gt;&lt;br&gt;<strong>Clinical criteria:</strong>&lt;br&gt;Patien must have an antral follicle count of 20 or less.&lt;br&gt;&lt;br&gt;<strong>Treatment criteria:</strong>&lt;br&gt;Patien must be undergoing treatment as described in items 13200, 13201 or 13202 of the Health Insurance (General Medical Services Table) Regulations, AND&lt;br&gt;Patien must be undergoing a gonadotrophin releasing hormone antagonist cycle.</td>
<td></td>
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</tr>
<tr>
<td>5816D</td>
<td>corifollitropin alfa 100 microgram/0.5 mL injection, 1 x 0.5 mL syringe</td>
<td>1</td>
<td>410.14</td>
<td>Elonva MK</td>
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<tr>
<td>5817E</td>
<td>corifollitropin alfa 150 microgram/0.5 mL injection, 1 x 0.5 mL syringe</td>
<td>1</td>
<td>673.51</td>
<td>Elonva MK</td>
</tr>
<tr>
<td>FOLLITROPIN ALFA</td>
<td><strong>Criteria for availability</strong>&lt;br&gt;Patients who are receiving medical treatment as described in items 13200, 13201, 13202 or 13203 of the Medicare Benefits Schedule</td>
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</tr>
<tr>
<td>6431L</td>
<td>follitropin alfa 300 international units / 0.5 mL (21.84 microgram/0.5 mL injection, 1 x 0.5 mL cartridge</td>
<td>1</td>
<td>145.20</td>
<td>Gonal-f Pen SG</td>
</tr>
<tr>
<td>6432M</td>
<td>follitropin alfa 450 international units / 0.75 mL (32.76 microgram/0.75 mL injection, 1 x 0.75 mL cartridge</td>
<td>1</td>
<td>217.80</td>
<td>Gonal-f Pen SG</td>
</tr>
<tr>
<td>6433N</td>
<td>follitropin alfa 900 international units / 1.5 mL (65.52 microgram/1.5 mL injection, 1 x 1.5 mL cartridge</td>
<td>1</td>
<td>435.60</td>
<td>Gonal-f Pen SG</td>
</tr>
<tr>
<td>FOLLITROPIN BETA</td>
<td><strong>Criteria for availability</strong>&lt;br&gt;Patients who are receiving medical treatment as described in items 13200, 13201, 13202 or 13203 of the Medicare Benefits Schedule</td>
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</tr>
<tr>
<td>6335K</td>
<td>follitropin beta 300 international units/0.36 mL injection, 1 x 0.36 mL</td>
<td>1</td>
<td>150.00</td>
<td>Puregon 300 IU/0.36 MK</td>
</tr>
</tbody>
</table>
**SECTION 100 (IVF/GIFT TREATMENT)**

<table>
<thead>
<tr>
<th>Code</th>
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<th>Price ex manufacturer $/mL</th>
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</tr>
</thead>
<tbody>
<tr>
<td>6336L</td>
<td>follitropin beta 600 international units/0.72 mL injection, 1 x 0.72 mL cartridge</td>
<td>1</td>
<td>292.72</td>
<td>Puregon 600 IU/0.72 mL MK</td>
</tr>
<tr>
<td>6464F</td>
<td>follitropin beta 900 international units/1.08 mL injection, 1 x 1.08 mL cartridge</td>
<td>1</td>
<td>435.15</td>
<td>Puregon 900 IU/1.08 mL MK</td>
</tr>
</tbody>
</table>

**GANIRELIX**

**Criteria for availability**

For the prevention of premature luteinisation and ovulation in patients undergoing controlled ovarian stimulation, followed by oocyte pick-up and assisted reproductive techniques as described in items 13200, 13201, 13202 or 13203 of the Medicare Benefits Schedule

**Note**
Supply of these items is through an accredited IVF/GIFT clinic. For enquiries relating to the IVF/GIFT Program, medical practitioners should contact Medicare Australia on 1800 700 270.

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>Price ex manufacturer $/mL</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>9583J</td>
<td>ganirelix 250 microgram/0.5 mL injection, 1 x 0.5 mL syringe</td>
<td>1</td>
<td>46.08</td>
<td>Orgalutran MK</td>
</tr>
<tr>
<td>9584K</td>
<td>ganirelix 250 microgram/0.5 mL injection, 5 x 0.5 mL syringes</td>
<td>1</td>
<td>230.40</td>
<td>Orgalutran MK</td>
</tr>
</tbody>
</table>

**GONADOTROPHIN CHORIONIC HUMAN**

**Criteria for availability**

Patients who are receiving medical treatment as described in items 13200, 13201, 13202 or 13203 of the Medicare Benefits Schedule

**Note**
Supply of these items is through an accredited IVF/GIFT clinic. For enquiries relating to the IVF/GIFT Program, medical practitioners should contact Medicare Australia on 1800 700 270.

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>Price ex manufacturer $/mL</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>6178E</td>
<td>gonadotrophin chorionic human 1500 international units injection [3 x 1500 international units ampoules] (&amp;) inert substance diluent [3 x 1 mL ampoules], 1 pack</td>
<td>1</td>
<td>39.57</td>
<td>Pregnyl MK</td>
</tr>
<tr>
<td>6181H</td>
<td>gonadotrophin chorionic human 5000 international units injection [1 x 5000 international units ampoule] (&amp;) inert substance diluent [1 x 1 mL ampoule], 1 pack</td>
<td>1</td>
<td>11.49</td>
<td>Pregnyl MK</td>
</tr>
</tbody>
</table>

**GONADOTROPHIN-MENOPAUSAL HUMAN**

**Criteria for availability**

Patients who are receiving medical treatment as described in items 13200, 13201, 13202 or 13203 of the Medicare Benefits Schedule

**Note**
Supply of these items is through an accredited IVF/GIFT clinic. For enquiries relating to the IVF/GIFT Program, medical practitioners should contact Medicare Australia on 1800 700 270.

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
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<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>2038G</td>
<td>gonadotrophin-menopausal human 1200 international units injection [1 x 1200 international units vial] (&amp;) inert substance diluent [2 x 1 mL syringes], 1 pack</td>
<td>1</td>
<td>531.18</td>
<td>Menopur 1200 FP</td>
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<tr>
<td>2036E</td>
<td>gonadotrophin-menopausal human 600 international units injection [1 x 600 international units vial] (&amp;) inert substance diluent [1 x 1 mL syringe], 1 pack</td>
<td>1</td>
<td>265.59</td>
<td>Menopur 600 FP</td>
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</tbody>
</table>

**NAFARELIN**

**Criteria for availability**

For the prevention of premature luteinisation and ovulation in patients undergoing controlled ovarian stimulation, followed by oocyte pick-up and assisted reproductive techniques as described in items 13200, 13201, 13202 or 13203 of the Medicare Benefits Schedule

**Note**
Supply of this item is through an accredited IVF/GIFT clinic. For enquiries relating to the IVF/GIFT Program, medical practitioners should contact Medicare Australia on 1800 700 270.

<table>
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<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>Price ex manufacturer $/mL</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>5815C</td>
<td>nafarelin 200 microgram/actuation nasal spray, 60 actuations</td>
<td>1</td>
<td>106.00</td>
<td>Synarel PF</td>
</tr>
</tbody>
</table>

**PROGESTERONE**

**Criteria for availability**

Luteal support as part of an assisted reproductive technology (ART) treatment programme for infertile women

**Clinical criteria:**

The treatment must be for luteal phase support,

**AND**

Patient must be receiving medical treatment as described in items 13200 or 13201 of the Health Insurance (General Medical Services Table) Regulations.

The luteal phase is defined as the time span from embryo transfer until implantation confirmed by positive B-hCG measurement.

**Note**
### PROGESTERONE

**Criteria for availability**

Luteal support as part of an assisted reproductive technology (ART) treatment programme for infertile women

**Clinical criteria:**

The treatment must be for luteal phase support,

**AND**

Patient must be receiving medical treatment as described in items 13200 or 13201 of the Health Insurance (General Medical Services Table) Regulations.

The luteal phase is defined as the time span from embryo transfer until implantation confirmed by positive B-hCG measurement.

**Note**

Supply of these items is through an accredited IVF/GIFT clinic. For enquiries relating to the IVF/GIFT Program, medical practitioners should contact the Department of Human Services on 1800 700 270.

**Note**

Special Pricing Arrangements apply.

<table>
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<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
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<th>Brand Name and Manufacturer</th>
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<tr>
<td>9608Q</td>
<td>progesterone 100 mg pessary, 15</td>
<td>1</td>
<td>50.40</td>
<td>Oripro ON</td>
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<tr>
<td>10116K</td>
<td>progesterone 100 mg pessary, 21</td>
<td>1</td>
<td>49.39</td>
<td>Endometrin FP</td>
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<tr>
<td>9609R</td>
<td>progesterone 200 mg pessary, 15</td>
<td>1</td>
<td>55.60</td>
<td>Oripro ON</td>
</tr>
<tr>
<td>6366C</td>
<td>progesterone 8% vaginal gel, 15 applications</td>
<td>1</td>
<td>148.50</td>
<td>Crinone 8% SG</td>
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</table>
### OPIATE DEPENDENCE TREATMENT PROGRAM

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
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<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td></td>
<td><strong>BUPRENORPHINE</strong></td>
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<td></td>
<td><strong>Criteria for availability</strong></td>
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<tr>
<td></td>
<td>Treatment of opiate dependence, including maintenance and detoxification (withdrawal), within a framework of medical, social and psychological treatment</td>
<td></td>
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</tr>
<tr>
<td></td>
<td><strong>Note</strong></td>
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</tr>
<tr>
<td></td>
<td>Treatment must be in accordance with the law of the relevant State or Territory.</td>
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<td></td>
<td><strong>Note</strong></td>
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<tr>
<td></td>
<td>Shared Care Model:</td>
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<tr>
<td></td>
<td>For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.</td>
<td></td>
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<tr>
<td>6308B</td>
<td>buprenorphine 2 mg tablet, 7</td>
<td>1</td>
<td>10.50</td>
<td>Subutex</td>
</tr>
<tr>
<td>6307Y</td>
<td>buprenorphine 400 microgram tablet, 7</td>
<td>1</td>
<td>6.16</td>
<td>Subutex</td>
</tr>
<tr>
<td>6309C</td>
<td>buprenorphine 8 mg tablet, 7</td>
<td>1</td>
<td>30.10</td>
<td>Subutex</td>
</tr>
<tr>
<td></td>
<td><strong>BUPRENORPHINE + NALOXONE</strong></td>
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</tr>
<tr>
<td></td>
<td><strong>Criteria for availability</strong></td>
<td></td>
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</tr>
<tr>
<td></td>
<td>Treatment of opiate dependence within a framework of medical, social and psychological treatment</td>
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<tr>
<td></td>
<td><strong>Caution</strong></td>
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<tr>
<td></td>
<td>Buprenorphine with naloxone soluble film and buprenorphine with naloxone sublingual tablet do not meet all the criteria for bioequivalence. Patients being switched between sublingual tablets and soluble films may therefore require a dosage adjustment.</td>
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<tr>
<td></td>
<td><strong>Note</strong></td>
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<td></td>
</tr>
<tr>
<td></td>
<td>Treatment must be in accordance with the law of the relevant State or Territory.</td>
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<tr>
<td></td>
<td><strong>Note</strong></td>
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<tr>
<td></td>
<td>Shared Care Model:</td>
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<tr>
<td></td>
<td>For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.</td>
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<tr>
<td>9749D</td>
<td>buprenorphine 2 mg + naloxone microgram film: sublingual, 28 films</td>
<td>1</td>
<td>46.20</td>
<td>Suboxone Film 2/0.5</td>
</tr>
<tr>
<td>9750E</td>
<td>buprenorphine 8 mg + naloxone 2 mg film: sublingual, 28 films</td>
<td>1</td>
<td>132.44</td>
<td>Suboxone Film 8/2</td>
</tr>
<tr>
<td></td>
<td><strong>METHADONE</strong></td>
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<tr>
<td></td>
<td><strong>Criteria for availability</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Treatment of opiate dependence in accordance with the law of the relevant State or Territory</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>Caution</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>The risk of drug dependence is high.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>Note</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Shared Care Model:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6172W</td>
<td>methadone hydrochloride 5 mg/mL oral liquid, 1000 mL</td>
<td>1</td>
<td>33.20</td>
<td>a Aspen Methadone Syrup</td>
</tr>
<tr>
<td>6171T</td>
<td>methadone hydrochloride 5 mg/mL oral liquid, 200 mL</td>
<td>1</td>
<td>7.91</td>
<td>a Aspen Methadone Syrup</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>a Biodone Forte</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>a Biodone Forte</td>
</tr>
</tbody>
</table>
Section 3 - Container Prices, Fees, Standard Packs and Prices for Ready Prepared Pharmaceutical Benefits

CONTAINER PRICES FOR QUANTITIES OF READY PREPARED BENEFITS LESS THAN THE STANDARD PACK:

<table>
<thead>
<tr>
<th>Category</th>
<th>Size</th>
<th>Price</th>
</tr>
</thead>
<tbody>
<tr>
<td>Injectables</td>
<td>150 mL</td>
<td>$0.81</td>
</tr>
<tr>
<td>Other Items</td>
<td>25 mL</td>
<td>$0.32</td>
</tr>
</tbody>
</table>

(The 25 mL is the most commonly used size)

FEES:

<table>
<thead>
<tr>
<th>Fee</th>
<th>Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dispensing Fee for Ready Prepared Benefits</td>
<td>$6.76</td>
</tr>
<tr>
<td>Dangerous Drug Fee</td>
<td>$2.71</td>
</tr>
<tr>
<td>Additional Fee for Agreed Price Ready Prepared Benefits</td>
<td>$1.15</td>
</tr>
</tbody>
</table>

NOTE -

Standard packs and prices (including mark-up, but without dispensing fee and dangerous drug fee) are for items against the price of which an asterisk (*) is shown in Section 2 of the Schedule.
<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Form/Strength</th>
<th>Pack and Price</th>
<th>Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>8048N</td>
<td>abciximab 10 mg/5 mL injection, 1 x 5 mL vial</td>
<td>1@ 482.23</td>
<td>LY</td>
</tr>
<tr>
<td>1003T</td>
<td>aciclovir 200 mg tablet, 25</td>
<td>25@ 14.80</td>
<td>AF, GN, SZ</td>
</tr>
<tr>
<td>1003T</td>
<td>aciclovir 200 mg tablet, 25</td>
<td>25@ 15.99</td>
<td>GK</td>
</tr>
<tr>
<td>2014B</td>
<td>alginic sodium 500 mg/10 mL + calcium carbonate 160 mg/10 mL + sodium bicarbonate 267 mg/10 mL oral liquid, 500 mL</td>
<td>1@ 4.13</td>
<td>RC</td>
</tr>
<tr>
<td>1557Y</td>
<td>allopurinol 100 mg tablet, 100</td>
<td>100@ 2.65</td>
<td>AF</td>
</tr>
<tr>
<td>2159P</td>
<td>aluminium hydroxide 250 mg/5 mL + magnesium hydroxide 120 mg/5 mL + magnesium trisilicate 120 mg/5 mL oral liquid, 500 mL</td>
<td>1@ 5.64</td>
<td>FM</td>
</tr>
<tr>
<td>2157M</td>
<td>ALUMINIUM HYDROXIDE with MAGNESIUM HYDROXIDE Oral suspension 200 mg-200 mg per 5 mL, 500 mL</td>
<td>1@ 5.64</td>
<td>JT</td>
</tr>
<tr>
<td>3417W</td>
<td>amino acid formula with fat, carbohydrate, vitamins, minerals and trace elements without methionine and supplemented with docosahexaenoic acid oral liquid, 36 x 125 mL cans</td>
<td>1@ 625.39</td>
<td>SB</td>
</tr>
<tr>
<td>9330C</td>
<td>amino acid formula with fat, carbohydrate, vitamins, minerals and trace elements without phenylalanine and tyrosine, and supplemented with docosahexaenoic acid oral liquid, 36 x 125 mL cans</td>
<td>1@ 625.39</td>
<td>SB</td>
</tr>
<tr>
<td>8678R</td>
<td>amino acid formula without phenylalanine 1 g tablet, 75</td>
<td>1@ 59.19</td>
<td>SB</td>
</tr>
<tr>
<td>8554F</td>
<td>amino acid formula without phenylalanine 500 mg capsule, 200</td>
<td>1@ 79.37</td>
<td>SB</td>
</tr>
<tr>
<td>2347M</td>
<td>amino acid formula without phenylalanine oral liquid: powder for, 30 x 20 g sachets</td>
<td>1@ 208.07</td>
<td>SB</td>
</tr>
<tr>
<td>8479G</td>
<td>amino acid formula with vitamins, minerals and polyunsaturated fatty acids without phenylalanine oral liquid: powder for, 400 g</td>
<td>1@ 87.15</td>
<td>SB</td>
</tr>
<tr>
<td>9438R</td>
<td>amino acid formula with vitamins and minerals without lysine and low in tryptophan oral liquid: powder for, 30 x 24 g sachets</td>
<td>1@ 526.99</td>
<td>VF</td>
</tr>
<tr>
<td>5484P</td>
<td>amino acid formula with vitamins and minerals without lysine and low in tryptophan oral liquid: powder for, 30 x 25 g sachets</td>
<td>1@ 787.00</td>
<td>VF</td>
</tr>
<tr>
<td>2650L</td>
<td>amino acid formula with vitamins and minerals without lysine and low in tryptophan oral liquid: powder for, 400 g</td>
<td>1@ 95.36</td>
<td>SB</td>
</tr>
<tr>
<td>2646G</td>
<td>amino acid formula with vitamins and minerals without lysine and low in tryptophan oral liquid: powder for, 500 g</td>
<td>1@ 222.29</td>
<td>SB</td>
</tr>
<tr>
<td>3444G</td>
<td>amino acid formula with vitamins and minerals without methionine, threonine and valine and low in isoleucine oral liquid: powder for, 30 x 24 g sachets</td>
<td>1@ 526.99</td>
<td>VF</td>
</tr>
<tr>
<td>3443F</td>
<td>amino acid formula with vitamins and minerals without methionine, threonine and valine and low in isoleucine oral liquid: powder for, 30 x 25 g sachets</td>
<td>1@ 772.99</td>
<td>VF</td>
</tr>
<tr>
<td>8058D</td>
<td>amino acid formula with vitamins and minerals without methionine, threonine and valine and low in isoleucine oral liquid: powder for, 400 g</td>
<td>1@ 95.36</td>
<td>SB</td>
</tr>
<tr>
<td>8059E</td>
<td>amino acid formula with vitamins and minerals without methionine, threonine and valine and low in isoleucine oral liquid: powder for, 500 g</td>
<td>1@ 222.29</td>
<td>SB</td>
</tr>
<tr>
<td>8061G</td>
<td>AMINO ACID FORMULA with VITAMINS and MINERALS without METHIONINE, THREONINE and VALINE and low in ISOLEUCINE Oral liquid 130 mL, 30, 1</td>
<td>1@ 337.29</td>
<td>SB</td>
</tr>
<tr>
<td>1923F</td>
<td>AMINO ACID FORMULA with VITAMINS and MINERALS without METHIONINE, THREONINE and VALINE and low in ISOLEUCINE Oral liquid 125 mL, 30, 1</td>
<td>1@ 772.99</td>
<td>VF</td>
</tr>
<tr>
<td>9133Q</td>
<td>amino acid formula with vitamins and minerals without methionine oral liquid, 30 x 130 mL cans</td>
<td>1@ 772.99</td>
<td>VF</td>
</tr>
<tr>
<td>2640Y</td>
<td>amino acid formula with vitamins and minerals without methionine oral liquid, 30 x 174 mL pouches</td>
<td>1@ 1018.99</td>
<td>VF</td>
</tr>
<tr>
<td>2639X</td>
<td>amino acid formula with vitamins and minerals without methionine oral liquid, 30 x 87 mL pouches</td>
<td>1@ 526.99</td>
<td>VF</td>
</tr>
<tr>
<td>8677Q</td>
<td>amino acid formula with vitamins and minerals without methionine oral liquid: powder for, 30 x 24 g sachets</td>
<td>1@ 526.99</td>
<td>VF</td>
</tr>
<tr>
<td>8744F</td>
<td>amino acid formula with vitamins and minerals without methionine oral liquid: powder for, 30 x 25 g sachets</td>
<td>1@ 772.99</td>
<td>VF</td>
</tr>
<tr>
<td>8417B</td>
<td>amino acid formula with vitamins and minerals without methionine oral liquid: powder for, 400 g</td>
<td>1@ 95.36</td>
<td>SB</td>
</tr>
<tr>
<td>8328H</td>
<td>amino acid formula with vitamins and minerals without methionine oral liquid: powder for, 500 g</td>
<td>1@ 222.29</td>
<td>SB</td>
</tr>
<tr>
<td>8416Y</td>
<td>AMINO ACID FORMULA with VITAMINS and MINERALS without METHIONINE Oral liquid 125 mL, 30, 1</td>
<td>1@ 337.29</td>
<td>SB</td>
</tr>
<tr>
<td>1548L</td>
<td>AMINO ACID FORMULA with VITAMINS and MINERALS without METHIONINE Oral liquid 125 mL, 30, 1</td>
<td>1@ 1030.64</td>
<td>SB</td>
</tr>
<tr>
<td>9132P</td>
<td>amino acid formula with vitamins and minerals without phenylalanine and tyrosine oral liquid, 30 x 130 mL cans</td>
<td>1@ 772.99</td>
<td>VF</td>
</tr>
<tr>
<td>2701E</td>
<td>amino acid formula with vitamins and minerals without phenylalanine</td>
<td>1@ 1018.99</td>
<td>VF</td>
</tr>
<tr>
<td>Code</td>
<td>Name, Form/Strength</td>
<td>Pack and Price</td>
<td>Manufacturer</td>
</tr>
<tr>
<td>--------</td>
<td>-------------------------------------------------------------------------------------</td>
<td>----------------</td>
<td>--------------</td>
</tr>
<tr>
<td>2674R</td>
<td>amino acid formula with vitamins and minerals without phenylalanine and tyrosine oral liquid, 30 x 174 mL pouches</td>
<td>1@ 526.99</td>
<td>VF</td>
</tr>
<tr>
<td>8631G</td>
<td>amino acid formula with vitamins and minerals without phenylalanine and tyrosine oral liquid, powder for, 30 x 24 g sachets</td>
<td>1@ 526.99</td>
<td>VF</td>
</tr>
<tr>
<td>8667E</td>
<td>amino acid formula with vitamins and minerals without phenylalanine and tyrosine oral liquid, powder for, 30 x 25 g sachets</td>
<td>1@ 772.99</td>
<td>VF</td>
</tr>
<tr>
<td>9395L</td>
<td>amino acid formula with vitamins and minerals without phenylalanine and tyrosine oral liquid, powder for, 30 x 29 g sachets</td>
<td>1@ 448.51</td>
<td>SB</td>
</tr>
<tr>
<td>8445L</td>
<td>amino acid formula with vitamins and minerals without phenylalanine and tyrosine oral liquid, powder for, 400 g</td>
<td>1@ 95.36</td>
<td>SB</td>
</tr>
<tr>
<td>3078B</td>
<td>amino acid formula with vitamins and minerals without phenylalanine and tyrosine oral liquid: powder for, 500 g</td>
<td>1@ 337.29</td>
<td>SB</td>
</tr>
<tr>
<td>8446M</td>
<td>AMINO ACID FORMULA with VITAMINS and MINERALS without PHENYLALANINE and TYROSINE Oral liquid 125 mL, 30, 1</td>
<td>1@ 222.29</td>
<td>SB</td>
</tr>
<tr>
<td>8746H</td>
<td>amino acid formula with vitamins and minerals without phenylalanine oral liquid, 18 x 250 mL cans</td>
<td>18@ 261.37</td>
<td>SB</td>
</tr>
<tr>
<td>9021T</td>
<td>amino acid formula with vitamins and minerals without phenylalanine oral liquid, 30 x 125 mL cans</td>
<td>1@ 514.34</td>
<td>SB</td>
</tr>
<tr>
<td>8846N</td>
<td>amino acid formula with vitamins and minerals without phenylalanine oral liquid, 30 x 130 mL cans</td>
<td>1@ 385.48</td>
<td>VF</td>
</tr>
<tr>
<td>2474F</td>
<td>amino acid formula with vitamins and minerals without phenylalanine oral liquid, 30 x 174 mL cans</td>
<td>1@ 511.90</td>
<td>VF</td>
</tr>
<tr>
<td>5483N</td>
<td>amino acid formula with vitamins and minerals without phenylalanine oral liquid, 30 x 85 g sachets</td>
<td>1@ 263.05</td>
<td>VF</td>
</tr>
<tr>
<td>2382J</td>
<td>amino acid formula with vitamins and minerals without phenylalanine oral liquid, 30 x 87 mL cans</td>
<td>1@ 257.09</td>
<td>VF</td>
</tr>
<tr>
<td>9396M</td>
<td>amino acid formula with vitamins and minerals without phenylalanine oral liquid, 36 x 125 mL cans</td>
<td>1@ 315.86</td>
<td>SB</td>
</tr>
<tr>
<td>9397N</td>
<td>amino acid formula with vitamins and minerals without phenylalanine oral liquid, 60 x 62.5 mL cans</td>
<td>1@ 526.47</td>
<td>SB</td>
</tr>
<tr>
<td>8555G</td>
<td>amino acid formula with vitamins and minerals without phenylalanine oral liquid: powder for, 30 x 24 g sachets</td>
<td>1@ 263.05</td>
<td>VF</td>
</tr>
<tr>
<td>8591E</td>
<td>amino acid formula with vitamins and minerals without phenylalanine oral liquid: powder for, 30 x 25 g sachets</td>
<td>1@ 385.68</td>
<td>VF</td>
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<tr>
<td>8804J</td>
<td>amino acid formula with vitamins and minerals without phenylalanine oral liquid: powder for, 30 x 27.8 g sachets</td>
<td>1@ 514.34</td>
<td>SB</td>
</tr>
<tr>
<td>8613H</td>
<td>amino acid formula with vitamins and minerals without phenylalanine oral liquid: powder for, 30 x 29 g sachets</td>
<td>1@ 221.42</td>
<td>SB</td>
</tr>
<tr>
<td>8727H</td>
<td>amino acid formula with vitamins and minerals without phenylalanine oral liquid: powder for, 30 x 50 g sachets</td>
<td>1@ 501.88</td>
<td>SB</td>
</tr>
<tr>
<td>2738D</td>
<td>amino acid formula with vitamins and minerals without phenylalanine oral liquid: powder for, 500 g</td>
<td>1@ 109.70</td>
<td>SB</td>
</tr>
<tr>
<td>2739E</td>
<td>amino acid formula with vitamins and minerals without phenylalanine oral semi-solid, 36 x 109 g jars</td>
<td>1@ 168.25</td>
<td>SB</td>
</tr>
<tr>
<td>2806Q</td>
<td>amino acid formula with vitamins and minerals without phenylalanine Sachets 18.2 g, 60, 1</td>
<td>1@ 615.44</td>
<td>SB</td>
</tr>
<tr>
<td>1411G</td>
<td>AMINO ACID FORMULA with VITAMINS and MINERALS without PHENYLALANINE Sachets 18.2 g, 60, 1</td>
<td>1@ 544.55</td>
<td>SB</td>
</tr>
<tr>
<td>1909L</td>
<td>AMINO ACID FORMULA with VITAMINS and MINERALS without PHENYLALANINE Sachets 34 g, 30, 1</td>
<td>1@ 511.90</td>
<td>VF</td>
</tr>
<tr>
<td>2375B</td>
<td>amino acid formula with vitamins and minerals without valine, leucine and isoleucine oral liquid, 30 x 130 mL cans</td>
<td>1@ 772.99</td>
<td>VF</td>
</tr>
<tr>
<td>2654Q</td>
<td>amino acid formula with vitamins and minerals without valine, leucine and isoleucine oral liquid, 30 x 174 mL pouches</td>
<td>1@ 1018.99</td>
<td>VF</td>
</tr>
<tr>
<td>2651M</td>
<td>amino acid formula with vitamins and minerals without valine, leucine and isoleucine oral liquid, 30 x 87 mL pouches</td>
<td>1@ 526.99</td>
<td>VF</td>
</tr>
<tr>
<td>8592F</td>
<td>amino acid formula with vitamins and minerals without valine, leucine and isoleucine oral liquid: powder for, 30 x 24 g sachets</td>
<td>1@ 526.99</td>
<td>VF</td>
</tr>
<tr>
<td>8632H</td>
<td>amino acid formula with vitamins and minerals without valine, leucine and isoleucine oral liquid: powder for, 30 x 25 g sachets</td>
<td>1@ 772.99</td>
<td>VF</td>
</tr>
<tr>
<td>8745G</td>
<td>amino acid formula with vitamins and minerals without valine, leucine and isoleucine oral liquid: powder for, 30 x 29 g sachets</td>
<td>1@ 448.51</td>
<td>SB</td>
</tr>
<tr>
<td>2380G</td>
<td>amino acid formula with vitamins and minerals without valine, leucine and isoleucine oral liquid: powder for, 400 g</td>
<td>1@ 95.36</td>
<td>SB</td>
</tr>
<tr>
<td>Code</td>
<td>Name, Form/Strength</td>
<td>Pack and Price</td>
<td>Manufacturer</td>
</tr>
<tr>
<td>--------</td>
<td>-------------------------------------------------------------------------------------</td>
<td>----------------</td>
<td>--------------</td>
</tr>
<tr>
<td>8057C</td>
<td>amino acid formula with vitamins and minerals without valine, leucine and isoleucine oral liquid: powder for, 500 g</td>
<td>1@ 337.29</td>
<td>SB</td>
</tr>
<tr>
<td>8260R</td>
<td></td>
<td>1@ 222.29</td>
<td>SB</td>
</tr>
<tr>
<td>8310J</td>
<td></td>
<td>1@ 666.39</td>
<td>SB</td>
</tr>
<tr>
<td>1546J</td>
<td>AMINO ACID FORMULA with VITAMINS and MINERALS without VALINE, LEUCINE and ISOLEUCINE Oral liquid 125 mL, 30, 1</td>
<td>1@ 1021.93</td>
<td>VF</td>
</tr>
<tr>
<td>1914R</td>
<td>AMINO ACID FORMULA with VITAMINS and MINERALS without VALINE, LEUCINE and ISOLEUCINE Sachets 34 g, 30, 1</td>
<td>1@ 625.39</td>
<td>SB</td>
</tr>
<tr>
<td>9499Y</td>
<td>amino acid formula with vitamins and minerals without valine, leucine and isoleucine with fat, carbohydrate and trace elements and supplemented with docosahexaenoic acid oral liquid, 36 cans</td>
<td>1@ 625.39</td>
<td>SB</td>
</tr>
<tr>
<td>1180D</td>
<td></td>
<td>1@ 44.34</td>
<td>SB</td>
</tr>
<tr>
<td>1192R</td>
<td></td>
<td>1@ 44.34</td>
<td>SB</td>
</tr>
<tr>
<td>1521C</td>
<td></td>
<td>1@ 43.77</td>
<td>SB</td>
</tr>
<tr>
<td>2250K</td>
<td></td>
<td>1@ 43.77</td>
<td>AB</td>
</tr>
<tr>
<td>8574G</td>
<td></td>
<td>1@ 44.34</td>
<td>AB</td>
</tr>
<tr>
<td>8575H</td>
<td></td>
<td>1@ 44.34</td>
<td>AB</td>
</tr>
<tr>
<td>8754R</td>
<td></td>
<td>1@ 44.34</td>
<td>SB</td>
</tr>
<tr>
<td>8755T</td>
<td></td>
<td>1@ 44.34</td>
<td>SB</td>
</tr>
<tr>
<td>1545H</td>
<td>amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids and medium chain triglycerides oral liquid: powder for, 400 g</td>
<td>1@ 44.65</td>
<td>SB</td>
</tr>
<tr>
<td>2900P</td>
<td></td>
<td>1@ 45.18</td>
<td>NT</td>
</tr>
<tr>
<td>2928D</td>
<td></td>
<td>1@ 45.18</td>
<td>NT</td>
</tr>
<tr>
<td>5466Q</td>
<td></td>
<td>1@ 45.18</td>
<td>SB</td>
</tr>
<tr>
<td>5467R</td>
<td></td>
<td>1@ 45.18</td>
<td>SB</td>
</tr>
<tr>
<td>2246F</td>
<td>amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids oral liquid: powder for, 400 g</td>
<td>1@ 45.18</td>
<td>SB</td>
</tr>
<tr>
<td>2560R</td>
<td></td>
<td>1@ 45.18</td>
<td>SB</td>
</tr>
<tr>
<td>9339M</td>
<td></td>
<td>1@ 45.18</td>
<td>AB</td>
</tr>
<tr>
<td>9340N</td>
<td></td>
<td>1@ 45.18</td>
<td>AB</td>
</tr>
<tr>
<td>8736T</td>
<td>amisulpride 100 mg/mL oral liquid, 60 mL</td>
<td>1@ 71.16</td>
<td>SW</td>
</tr>
<tr>
<td>9386B</td>
<td>amylpectin modified long chain oral liquid: powder for, 30 x 60 g sachets</td>
<td>1@ 186.47</td>
<td>VF</td>
</tr>
<tr>
<td>10036F</td>
<td>arachidonic acid and docosahexaenoic acid with carbohydrate containing 200 mg arachidonic acid and 100 mg docosahexaenoic acid oral liquid: powder for, 30 x 4 g sachets</td>
<td>1@ 91.10</td>
<td>VF</td>
</tr>
<tr>
<td>5482M</td>
<td>arginine with carbohydrate containing 2 g arginine oral liquid: powder for, 30 x 4 g sachets</td>
<td>1@ 191.10</td>
<td>VF</td>
</tr>
<tr>
<td>9437Q</td>
<td>arginine with carbohydrate containing 500 mg arginine oral liquid: powder for, 30 x 7.6 g sachets</td>
<td>1@ 254.17</td>
<td>VF</td>
</tr>
<tr>
<td>10093F</td>
<td>arginine with carbohydrate containing 5 g arginine oral liquid: powder for, 30 x 7.6 g sachets</td>
<td>1@ 254.17</td>
<td>VF</td>
</tr>
<tr>
<td>9092M</td>
<td>atomoxetine 10 mg capsule, 28</td>
<td>28@ 107.38</td>
<td>LY</td>
</tr>
<tr>
<td>9093N</td>
<td>atomoxetine 18 mg capsule, 28</td>
<td>28@ 107.38</td>
<td>LY</td>
</tr>
<tr>
<td>9094P</td>
<td>atomoxetine 25 mg capsule, 28</td>
<td>28@ 107.38</td>
<td>LY</td>
</tr>
<tr>
<td>9095Q</td>
<td>atomoxetine 40 mg capsule, 28</td>
<td>28@ 107.38</td>
<td>LY</td>
</tr>
<tr>
<td>9096R</td>
<td>atomoxetine 60 mg capsule, 28</td>
<td>28@ 107.38</td>
<td>LY</td>
</tr>
<tr>
<td>1140B</td>
<td>Bacillus Calmette and Guerin-Connaught strain 660 million colony forming units injection [1 x 81 mg vial] (&amp;) inert substance diluent [1 x 3 mL vial], 1 pack</td>
<td>1@ 151.15</td>
<td>SW</td>
</tr>
<tr>
<td>2647H</td>
<td>benzylpenicillin 3 g injection, 1 x 3 g vial</td>
<td>1@ 8.31</td>
<td>CS</td>
</tr>
<tr>
<td>3399X</td>
<td>benzylpenicillin 600 mg injection, 1 x 600 mg vial</td>
<td>1@ 8.31</td>
<td>CS</td>
</tr>
<tr>
<td>1775K</td>
<td>benzylpenicillin 600 mg injection, 1 x 600 mg vial</td>
<td>1@ 4.83</td>
<td>CS</td>
</tr>
<tr>
<td>3398W</td>
<td>benzylpenicillin 600 mg injection, 1 x 600 mg vial</td>
<td>1@ 4.83</td>
<td>CS</td>
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<tr>
<td>2812B</td>
<td>betamethasone (as valerate) 0.02% (200 microgram/g) cream, 100 g</td>
<td>1@ 12.34</td>
<td>QA</td>
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<tr>
<td>2812C</td>
<td>betamethasone (as valerate) 0.02% (200 microgram/g) cream, 100 g</td>
<td>1@ 10.13</td>
<td>MK</td>
</tr>
<tr>
<td>2812D</td>
<td>betamethasone (as valerate) 0.02% (200 microgram/g) cream, 100 g</td>
<td>1@ 8.90</td>
<td>FM, FR</td>
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<tr>
<td>2544X</td>
<td>biperiden hydrochloride 2 mg tablet, 100</td>
<td>28@ 7.23</td>
<td>LM</td>
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<tr>
<td>1260H</td>
<td>bisacodyl 10 mg suppository, 10</td>
<td>1@ 4.84</td>
<td>PP</td>
</tr>
<tr>
<td>1260H</td>
<td>bisacodyl 10 mg suppository, 10</td>
<td>1@ 5.34</td>
<td>BY</td>
</tr>
<tr>
<td>5030D</td>
<td></td>
<td>1@ 5.34</td>
<td>BY</td>
</tr>
<tr>
<td>5030D</td>
<td></td>
<td>1@ 4.84</td>
<td>PP</td>
</tr>
<tr>
<td>5030H</td>
<td></td>
<td>1@ 5.34</td>
<td>BY</td>
</tr>
<tr>
<td>5030H</td>
<td></td>
<td>1@ 4.84</td>
<td>PP</td>
</tr>
<tr>
<td>Code</td>
<td>Name, Form/Strength</td>
<td>Pack and Price</td>
<td>Manufacturer</td>
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<tr>
<td>1258F</td>
<td>bisacodyl 10 mg suppository, 12</td>
<td>1@ 3.97</td>
<td>PP</td>
</tr>
<tr>
<td>5304E</td>
<td>1@ 3.97</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5308J</td>
<td>1@ 3.97</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1443Y</td>
<td>bromocriptine 2.5 mg tablet, 30</td>
<td>30@ 12.50</td>
<td>NV</td>
</tr>
<tr>
<td>10015D</td>
<td>budesonide 100 microgram/actuation + eformoterol fumarate dihydrate 3 microgram/actuation inhalation: pressurised, 120 actuations</td>
<td>1@ 26.17</td>
<td>AP</td>
</tr>
<tr>
<td>10018G</td>
<td>budesonide 200 microgram/actuation + eformoterol fumarate dihydrate 6 microgram/actuation inhalation: pressurised, 120 actuations</td>
<td>1@ 42.06</td>
<td>AP</td>
</tr>
<tr>
<td>10024N</td>
<td>budesonide 50 microgram/actuation + eformoterol fumarate dihydrate 3 microgram/actuation inhalation: pressurised, 120 actuations</td>
<td>1@ 24.02</td>
<td>AP</td>
</tr>
<tr>
<td>3116B</td>
<td>CALCIUM Tablet (chewable) 500 mg (as carbonate), 60</td>
<td>60@ 5.62</td>
<td>IA, PP</td>
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<tr>
<td>2422L</td>
<td>CARBAMAZEPINE Tablet 100 mg, 100</td>
<td>100@ 6.04</td>
<td>SZ</td>
</tr>
<tr>
<td>2422L</td>
<td>CARBAMAZEPINE Tablet 100 mg, 100</td>
<td>100@ 7.52</td>
<td>NV</td>
</tr>
<tr>
<td>5039F</td>
<td>100@ 7.52</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5039F</td>
<td>100@ 6.04</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1706T</td>
<td>CARBAMAZEPINE Tablet 200 mg, 100</td>
<td>100@ 12.77</td>
<td>NV</td>
</tr>
<tr>
<td>1706T</td>
<td>CARBAMAZEPINE Tablet 200 mg, 100</td>
<td>100@ 11.29</td>
<td>SZ</td>
</tr>
<tr>
<td>1724R</td>
<td>100@ 11.29</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1724R</td>
<td>100@ 12.77</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1153Q</td>
<td>carbimazole 5 mg tablet, 100</td>
<td>100@ 12.31</td>
<td>LM, PQ</td>
</tr>
<tr>
<td>8369L</td>
<td>carbohydrate, fat, vitamins, minerals and trace elements oral liquid: powder for, 400 g</td>
<td>1@ 38.97</td>
<td>SB</td>
</tr>
<tr>
<td>10050Y</td>
<td>carbohydrates, fat, vitamins, minerals, trace elements and supplemented with arachidonic acid and docosahexaenoic acid providing 100 kilocalories oral liquid: powder for 30 x 21.5 g sachets</td>
<td>1@ 60.46</td>
<td>VF</td>
</tr>
<tr>
<td>10039J</td>
<td>carbohydrates, fat, vitamins, minerals, trace elements and supplemented with arachidonic acid and docosahexaenoic acid providing 100 kilocalories oral liquid: powder for 30 x 43 g sachets</td>
<td>1@ 116.43</td>
<td>VF</td>
</tr>
<tr>
<td>2058H</td>
<td>carbomer 0.2% + triglyceride lipids 1% eye gel, 30 x 600 mg unit doses</td>
<td>1@ 9.89</td>
<td>BU</td>
</tr>
<tr>
<td>2090B</td>
<td>9.89</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2090B</td>
<td>9.89</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5502N</td>
<td>carborner-974 0.3% eye gel, 30 x 500 mg unit doses</td>
<td>1@ 9.88</td>
<td>AQ</td>
</tr>
<tr>
<td>8514D</td>
<td>9.88</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5504Q</td>
<td>carborner-980 0.2% (2 mg/g) eye drops, 30 x 0.6 mL unit doses</td>
<td>1@ 9.89</td>
<td>AQ</td>
</tr>
<tr>
<td>8578L</td>
<td>9.89</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5509Y</td>
<td>carmellose sodium 0.25% (1.5 mg/0.6 mL) eye drops, 24 x 0.6 mL unit doses</td>
<td>1@ 8.50</td>
<td>CX</td>
</tr>
<tr>
<td>8823J</td>
<td>8.50</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2338C</td>
<td>carmellose sodium 0.5% (2 mg/0.4 mL) eye drops, 30 x 0.4 mL unit doses</td>
<td>1@ 8.29</td>
<td>PP</td>
</tr>
<tr>
<td>2338C</td>
<td>8.29</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5506T</td>
<td>9.88</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5506T</td>
<td>8.29</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5561Q</td>
<td>carmellose sodium 0.5% + glycerol 0.9% eye drops, 30 x 0.4 mL unit doses</td>
<td>1@ 9.88</td>
<td>AG</td>
</tr>
<tr>
<td>9307W</td>
<td>9.88</td>
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<td></td>
</tr>
<tr>
<td>2324H</td>
<td>carmellose sodium 1% (4 mg/0.4 mL) eye drops, 30 x 0.4 mL unit doses</td>
<td>1@ 9.88</td>
<td>AG</td>
</tr>
<tr>
<td>2324H</td>
<td>9.88</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5505R</td>
<td>carmellose sodium 1% (4 mg/0.4 mL) eye drops, 30 x 0.4 mL unit doses</td>
<td>1@ 8.29</td>
<td>PP</td>
</tr>
<tr>
<td>5505R</td>
<td>8.29</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5510B</td>
<td>carmellose sodium 1% (6 mg/0.6 mL) eye gel, 28 x 0.6 mL unit doses</td>
<td>1@ 9.22</td>
<td>CX</td>
</tr>
<tr>
<td>8824K</td>
<td>9.22</td>
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<td></td>
</tr>
<tr>
<td>8315P</td>
<td>CEFEPIME Powder for injection 1 g (as hydrochloride), 1</td>
<td>1@ 8.22</td>
<td>AE, AF, HH, OE, SZ</td>
</tr>
<tr>
<td>8316Q</td>
<td>CEFEPIME Powder for injection 2 g (as hydrochloride), 1</td>
<td>1@ 15.68</td>
<td>AE, AF, HH, OE, SZ</td>
</tr>
<tr>
<td>1085D</td>
<td>cefotaxime 1 g injection, 1 x 1 g vial</td>
<td>1@ 1.64</td>
<td>SZ</td>
</tr>
<tr>
<td>5048Q</td>
<td>1@ 1.64</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1086E</td>
<td>cefotaxime 2 g injection, 1 x 2 g vial</td>
<td>1@ 3.02</td>
<td>SZ</td>
</tr>
<tr>
<td>5049R</td>
<td>1@ 3.02</td>
<td></td>
<td></td>
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<tr>
<td>1784X</td>
<td>cefetiaxone 1 g injection, 1 x 1 g vial</td>
<td>1@ 1.92</td>
<td>AE, HH, PP, RO, SZ</td>
</tr>
<tr>
<td>1785Y</td>
<td>cefetiaxone 2 g injection, 1 x 2 g vial</td>
<td>1@ 3.55</td>
<td>AE, AF, HH, PP, RO, SZ</td>
</tr>
<tr>
<td>1785Y</td>
<td>3.55</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1783W</td>
<td>cefetiaxone 500 mg injection, 1 x 500 mg vial</td>
<td>1@ 1.22</td>
<td>AE, PP</td>
</tr>
<tr>
<td>2655R</td>
<td>cephalixin 250 mg capsule, 20</td>
<td>20@ 1.13</td>
<td>AF, CH, CR, EA, GN,</td>
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<tr>
<td>Code</td>
<td>Name, Form/Strength</td>
<td>Pack and Price</td>
<td>Manufacturer</td>
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<td>------------------------------------------------------------------------------------</td>
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<tr>
<td>2655R</td>
<td>cephalexin 250 mg capsule, 20</td>
<td>20@ 5.45</td>
<td>AS</td>
</tr>
<tr>
<td>1797N</td>
<td>cephazolin 1 g injection, 5 x 1 g vials</td>
<td>5@ 5.13</td>
<td>AE, HH</td>
</tr>
<tr>
<td>1799Q</td>
<td>cephazolin 2 g injection, 1 x 2 g vial</td>
<td>5@ 5.13</td>
<td>AE, HH</td>
</tr>
<tr>
<td>5479J</td>
<td>cephazolin 500 mg injection, 5 x 500 mg vials</td>
<td>5@ 3.85</td>
<td>AE</td>
</tr>
<tr>
<td>9326W</td>
<td>cephazolin 500 mg injection, 5 x 500 mg vials</td>
<td>1@ 2.35</td>
<td>AS</td>
</tr>
<tr>
<td>1256D</td>
<td>chlorambucil 2 mg tablet, 25</td>
<td>25@ 36.84</td>
<td>AS</td>
</tr>
<tr>
<td>1163F</td>
<td>chlorthalidone 25 mg tablet, 50</td>
<td>50@ 5.88</td>
<td>LM</td>
</tr>
<tr>
<td>2957E</td>
<td>cholestyramine 4 g oral liquid: powder for, 50 x 4.7 g sachets</td>
<td>1@ 32.76</td>
<td>QA</td>
</tr>
<tr>
<td>9249T</td>
<td>ciprofloxacin 0.3% eye drops, 5 mL</td>
<td>1@ 12.06</td>
<td>AQ</td>
</tr>
<tr>
<td>1217C</td>
<td>ciprofloxacin 0.3% eye drops, 5 mL</td>
<td>1@ 12.06</td>
<td>AQ</td>
</tr>
<tr>
<td>5564W</td>
<td>ciprofloxacin 0.3% eye drops, 5 mL</td>
<td>1@ 127.40</td>
<td>VF</td>
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<tr>
<td>1808E</td>
<td>clonazepam 2.5 mg/mL oral liquid, 10 mL</td>
<td>1@ 4.31</td>
<td>RO</td>
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<tr>
<td>5339B</td>
<td>clonazepam 2 mg tablet, 100</td>
<td>100@ 12.32</td>
<td>AF</td>
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<tr>
<td>5342E</td>
<td>clonazepam 2 mg tablet, 100</td>
<td>100@ 14.25</td>
<td>RO</td>
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<tr>
<td>1806C</td>
<td>clonazepam 500 microgram tablet, 100</td>
<td>100@ 6.54</td>
<td>AF</td>
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<tr>
<td>1806B</td>
<td>clonazepam 500 microgram tablet, 100</td>
<td>100@ 8.25</td>
<td>RO</td>
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<tr>
<td>8785J</td>
<td>CODEINE PHOSPHATE with PARACETAMOL Tablet 30 mg-500 mg, 20</td>
<td>20@ 3.32</td>
<td>SW</td>
</tr>
<tr>
<td>8785J</td>
<td>CODEINE PHOSPHATE with PARACETAMOL Tablet 30 mg-500 mg, 20</td>
<td>20@ 0.92</td>
<td>AL, AV, FM, GQ, SZ, TX</td>
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<tr>
<td>8661W</td>
<td>cyclosporin 100 mg/mL oral liquid, 50 mL</td>
<td>1@ 353.12</td>
<td>NV</td>
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<tr>
<td>8660T</td>
<td>cyclosporin 100 mg capsule, 30</td>
<td>30@ 184.01</td>
<td>NV, S5</td>
</tr>
<tr>
<td>8657P</td>
<td>cyclosporin 10 mg capsule, 60</td>
<td>60@ 44.00</td>
<td>NV</td>
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<td>8658Q</td>
<td>cyclosporin 25 mg capsule, 30</td>
<td>30@ 45.41</td>
<td>NV, S5</td>
</tr>
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<td>8659R</td>
<td>cyclosporin 50 mg capsule, 30</td>
<td>30@ 94.48</td>
<td>NV, S5</td>
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<td>1270W</td>
<td>cyproterone acetate 50 mg tablet, 50</td>
<td>50@ 59.79</td>
<td>AF, EA, ER, GN, GX, HX, QA, SY</td>
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<tr>
<td>1270W</td>
<td>cyproterone acetate 50 mg tablet, 50</td>
<td>50@ 60.91</td>
<td>BN</td>
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<tr>
<td>9164H</td>
<td>cystine with carbohydrate containing 500 mg cystine oral liquid: powder for, 30 x 4 g sachets</td>
<td>1@ 127.40</td>
<td>VF</td>
</tr>
<tr>
<td>9319L</td>
<td>dabigatran etexilate 110 mg capsule, 10</td>
<td>10@ 15.59</td>
<td>BY</td>
</tr>
<tr>
<td>9323Q</td>
<td>dabigatran etexilate 75 mg capsule, 10</td>
<td>10@ 19.56</td>
<td>BY</td>
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<tr>
<td>9318K</td>
<td>dalteparin sodium 10 000 anti-Xa international units/mL injection, 10 x 1 mL syringes</td>
<td>10@ 84.57</td>
<td>PF</td>
</tr>
<tr>
<td>8957K</td>
<td>dalteparin sodium 12 500 anti-Xa international units/0.5 mL injection, 10 x 0.5 mL syringes</td>
<td>10@ 82.88</td>
<td>PF</td>
</tr>
<tr>
<td>8956L</td>
<td>dalteparin sodium 2500 anti-Xa international units/0.2 mL injection, 10 x 0.2 mL syringes</td>
<td>10@ 117.43</td>
<td>PF</td>
</tr>
<tr>
<td>8603T</td>
<td>dalteparin sodium 2500 anti-Xa international units/0.2 mL injection, 10 x 0.2 mL syringes</td>
<td>10@ 114.43</td>
<td>PF</td>
</tr>
<tr>
<td>8641T</td>
<td>dalteparin sodium 5000 anti-Xa international units/0.2 mL injection, 10 x 0.2 mL syringes</td>
<td>10@ 49.16</td>
<td>PF</td>
</tr>
<tr>
<td>8642W</td>
<td>dalteparin sodium 7500 anti-Xa international units/0.75 mL injection, 10 x 0.75 mL syringes</td>
<td>10@ 51.23</td>
<td>PF</td>
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<tr>
<td>8956J</td>
<td>desmopressin acetate 100 microgram/mL nasal drops, 2.5 mL</td>
<td>1@ 30.95</td>
<td>PF</td>
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<tr>
<td>Code</td>
<td>Name, Form/Strength</td>
<td>Pack and Price</td>
<td>Manufacturer</td>
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<tr>
<td>8711L</td>
<td>desmopressin acetate 10 microgram/actuation nasal spray, 60 actuations</td>
<td>1@ 77.31</td>
<td>FP</td>
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<tr>
<td>8662X</td>
<td>desmopressin acetate 200 microgram tablet, 30</td>
<td>30@ 57.83</td>
<td>FP</td>
</tr>
<tr>
<td>5521N</td>
<td>dextran-70 0.1% + hypromellose 0.3% eye drops, 28 x 0.4 mL unit doses</td>
<td>1@ 9.55</td>
<td>AQ</td>
</tr>
<tr>
<td>8299T</td>
<td></td>
<td>1@ 9.55</td>
<td>AQ</td>
</tr>
<tr>
<td>1302M</td>
<td>diclofenac sodium 100 mg suppository, 20</td>
<td>20@ 9.25</td>
<td>NV</td>
</tr>
<tr>
<td>5079H</td>
<td></td>
<td>20@ 9.25</td>
<td>NV</td>
</tr>
<tr>
<td>5363G</td>
<td></td>
<td>20@ 9.25</td>
<td>NV</td>
</tr>
<tr>
<td>5366K</td>
<td></td>
<td>20@ 9.25</td>
<td>NV</td>
</tr>
<tr>
<td>1299J</td>
<td>diclofenac sodium 25 mg tablet: enteric, 50 tablets</td>
<td>50@ 2.17</td>
<td>AF, CH, GN, QA, SZ, TW, TX</td>
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<tr>
<td>1299J</td>
<td>diclofenac sodium 25 mg tablet: enteric, 50 tablets</td>
<td>50@ 2.98</td>
<td>NV</td>
</tr>
<tr>
<td>5076E</td>
<td></td>
<td>50@ 2.17</td>
<td>AF, CH, GN, QA, SZ, TW, TX</td>
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<tr>
<td>5361E</td>
<td></td>
<td>50@ 2.98</td>
<td>NV</td>
</tr>
<tr>
<td>5364H</td>
<td></td>
<td>50@ 2.17</td>
<td>AF, CH, GN, QA, SZ, TW, TX</td>
</tr>
<tr>
<td>5364H</td>
<td></td>
<td>50@ 2.98</td>
<td>NV</td>
</tr>
<tr>
<td>3164M</td>
<td>digoxin 50 microgram/mL oral liquid, 60 mL</td>
<td>1@ 17.35</td>
<td>QA</td>
</tr>
<tr>
<td>10040K</td>
<td>docosahexaenoic acid with carbohydrate containing 200 mg docosahexaenoic acid oral liquid: powder for, 30 x 4g sachets</td>
<td>1@ 91.10</td>
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<td>doxycycline 100 mg capsule: modified release, 7 capsules</td>
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<td>enoxaparin sodium 100 mg/mL injection, 10 x 1 mL syringes</td>
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<td>eprosartan 400 mg tablet, 28</td>
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<td>28@ 8.86</td>
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<td>30@ 285.15</td>
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(APPLY WASTAGE FACTOR IN CALCULATING BROKEN QUANTITY PRICES)

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<td>5317W</td>
<td>ibuprofen 400 mg tablet, 30</td>
<td>30@ 2.77</td>
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<td>5318X</td>
<td>ibuprofen 400 mg tablet, 5 x 1 mL ampoules</td>
<td>5@ 17.02</td>
<td>BY</td>
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<tr>
<td>5323P</td>
<td>ibuprofen 25 mg capsule, 1</td>
<td>1@ 17.02</td>
<td>BY</td>
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<td>5368M</td>
<td>ibuprofen 50 mg capsule, 1</td>
<td>1@ 17.02</td>
<td>BY</td>
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<td>ibuprofen 100 mg suppository, 20</td>
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<td>2448W</td>
<td>idarubicin hydrochloride 10 mg capsule, 1</td>
<td>1@ 42.96</td>
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<td>2446R</td>
<td>idarubicin hydrochloride 5 mg capsule, 1</td>
<td>1@ 42.96</td>
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<td>2757D</td>
<td>indomethacin 100 mg suppository, 20</td>
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<td>AS</td>
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<td>5378C</td>
<td>indomethacin 25 mg capsule, 50</td>
<td>50@ 5.32</td>
<td>AS</td>
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<td>5377B</td>
<td>indomethacin 25 mg capsule, 50</td>
<td>50@ 5.32</td>
<td>AS</td>
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<td>5377B</td>
<td>indomethacin 25 mg capsule, 50</td>
<td>50@ 5.32</td>
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<td>insulin aspart 100 international units/mL injection, 1 x 10 mL vial</td>
<td>50@ 5.32</td>
<td>AS</td>
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<tr>
<td>5379D</td>
<td>insulin aspart 100 international units/mL injection, 5 x 3 mL vials</td>
<td>50@ 3.00</td>
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<td>8571D</td>
<td>insulin aspart 100 international units/mL injection, 5 x 3 mL vials</td>
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<td>insulin aspart 100 international units/mL injection, 1 x 10 mL vial</td>
<td>1@ 51.56</td>
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<td>insulin aspart 100 international units/mL injection, 1 x 10 mL vial</td>
<td>1@ 51.56</td>
<td>NF, NO</td>
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<td>9040T</td>
<td>insulin detemir 100 international units/mL injection, 5 x 3 mL vials</td>
<td>1@ 85.26</td>
<td>NF, NO</td>
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<td>9039R</td>
<td>insulin glargine 100 international units/mL injection, 5 x 3 mL vials</td>
<td>1@ 85.26</td>
<td>AV, SW</td>
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<tr>
<td>9224L</td>
<td>insulin glulisine 100 international units/mL injection, 1 x 10 mL vial</td>
<td>1@ 30.57</td>
<td>SW</td>
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<td>1921D</td>
<td>insulin glulisine 100 international units/mL injection, 5 x 3 mL vials</td>
<td>1@ 51.56</td>
<td>AV, SW</td>
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<td>1711C</td>
<td>insulin isophane bovine 100 international units/mL injection, 1 x 10 mL vial</td>
<td>1@ 78.66</td>
<td>AS</td>
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<tr>
<td>1533Q</td>
<td>insulin isophane human 100 international units/mL injection, 1 x 10 mL vial</td>
<td>1@ 25.48</td>
<td>LY, NO</td>
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<tr>
<td>1761Q</td>
<td>insulin isophane human 100 international units/mL injection, 5 x 3 mL vials</td>
<td>1@ 43.58</td>
<td>LY, NI, NO</td>
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<td>1763T</td>
<td>insulin isophane human 70 international units/mL injection, 5 x 3 mL vials</td>
<td>1@ 43.58</td>
<td>LY, NI, NO</td>
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<td>8084L</td>
<td>insulin lispro 100 international units/mL injection, 1 x 10 mL vial</td>
<td>1@ 30.57</td>
<td>LY</td>
</tr>
<tr>
<td>8212F</td>
<td>insulin lispro 100 international units/mL injection, 5 x 3 mL vials</td>
<td>1@ 51.56</td>
<td>KP, LY</td>
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<tr>
<td>8390N</td>
<td>insulin lispro 25 international units/mL injection, 5 x 3 mL vials</td>
<td>1@ 51.56</td>
<td>KP, LY</td>
</tr>
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<td>8874C</td>
<td>insulin lispro 50 international units/mL injection, 5 x 3 mL vials</td>
<td>1@ 51.56</td>
<td>KP, LY</td>
</tr>
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<td>1713E</td>
<td>insulin neutral bovine 100 international units/mL injection, 1 x 10 mL vial</td>
<td>1@ 78.66</td>
<td>AS</td>
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<td>1531N</td>
<td>insulin neutral human 100 international units/mL injection, 1 x 10 mL vial</td>
<td>1@ 25.48</td>
<td>LY, NO</td>
</tr>
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<td>1762R</td>
<td>insulin neutral human 100 international units/mL injection, 5 x 3 mL vials</td>
<td>1@ 43.58</td>
<td>LY, NO</td>
</tr>
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<td>1426C</td>
<td>insulin neutral human 30 international units/mL + insulin isophane human 70 units/mL injection, 5 x 3 mL vials</td>
<td>1@ 25.48</td>
<td>LY</td>
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<td>2062M</td>
<td>insulin neutral human 50 international units/mL + insulin isophane human 50 international units/mL injection, 5 x 3 mL vials</td>
<td>1@ 43.58</td>
<td>NO</td>
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<td>8180M</td>
<td>interferon alfa-2a 3 million international units/0.5 mL syringe</td>
<td>1@ 33.32</td>
<td>RO</td>
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<td>8181N</td>
<td>interferon alfa-2a 4.5 million international units/0.5 mL syringe</td>
<td>1@ 33.32</td>
<td>RO</td>
</tr>
<tr>
<td>8182P</td>
<td>interferon alfa-2a 6 million international units/0.5 mL syringe</td>
<td>1@ 51.66</td>
<td>RO</td>
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<td>8551C</td>
<td>interferon alfa-2a 6 million international units/0.5 mL syringe</td>
<td>1@ 51.66</td>
<td>RO</td>
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<tr>
<td>8183Q</td>
<td>interferon alfa-2a 6 million international units/0.5 mL syringe</td>
<td>1@ 67.66</td>
<td>RO</td>
</tr>
<tr>
<td>8552D</td>
<td>interferon alfa-2a 9 million international units/0.5 mL syringe</td>
<td>1@ 67.66</td>
<td>RO</td>
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<tr>
<td>8184R</td>
<td>interferon alfa-2a 9 million international units/0.5 mL syringe</td>
<td>1@ 99.94</td>
<td>RO</td>
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<td>8553E</td>
<td>interferon alfa-2b 18 million international units/1.2 mL injection, 1 x 1.2 mL cartridge</td>
<td>1@ 99.94</td>
<td>RO</td>
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<tr>
<td>8348J</td>
<td>interferon alfa-2b 18 million international units/1.2 mL injection, 1 x 1.2 mL cartridge</td>
<td>1@ 199.87</td>
<td>MK</td>
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<tr>
<td>8572E</td>
<td>interferon alfa-2b 30 million international units/1.2 mL injection, 1 x 1.2 mL cartridge</td>
<td>1@ 199.87</td>
<td>MK</td>
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<tr>
<td>8476D</td>
<td>interferon alfa-2b 30 million international units/1.2 mL injection, 1 x 1.2 mL cartridge</td>
<td>1@ 333.11</td>
<td>MK</td>
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<tr>
<td>8671J</td>
<td>ipratropium bromide 20 microgram/actuation inhalation: pressurised, 200 actuations</td>
<td>1@ 13.71</td>
<td>BY</td>
</tr>
<tr>
<td>1542E</td>
<td>ipratropium bromide 250 microgram/mL inhalation: solution, 30 x 1 mL ampoules</td>
<td>1@ 11.02</td>
<td>BY</td>
</tr>
<tr>
<td>1542E</td>
<td>ipratropium bromide 250 microgram/mL inhalation: solution, 30 x 1 mL ampoules</td>
<td>1@ 10.76</td>
<td>AF, PF, QA, TX</td>
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<tr>
<td>8238N</td>
<td>ipratropium bromide 500 microgram/mL inhalation: solution, 30 x 1 mL ampoules</td>
<td>1@ 12.72</td>
<td>AF, PF, QA, TX</td>
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<tr>
<td>8238N</td>
<td>ipratropium bromide 500 microgram/mL inhalation: solution, 30 x 1 mL ampoules</td>
<td>1@ 12.96</td>
<td>BY</td>
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<tr>
<td>10104T</td>
<td>iron (as ferric carboxymaltose) 500 mg/10 mL injection, 1 x 10 mL vial</td>
<td>1@ 155.23</td>
<td>VL</td>
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<tr>
<td>9436P</td>
<td>isoleucine with carbohydrate containing 1 g isoleucine oral liquid: powder for, 30 x 4 g sachets</td>
<td>1@ 140.14</td>
<td>VF</td>
</tr>
<tr>
<td>9134R</td>
<td>isoleucine with carbohydrate containing 50 mg isoleucine oral liquid:</td>
<td>1@ 127.40</td>
<td>VF</td>
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<tr>
<td>Code</td>
<td>Name, Form/Strength</td>
<td>Pack and Price</td>
<td>Manufacturer</td>
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<td>-------------------------------------------------------------------------------------------------------------</td>
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<tr>
<td>2588F</td>
<td>powder for, 30 x 4 g sachets</td>
<td>100@ 4.07</td>
<td>QA</td>
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<tr>
<td>2868Y</td>
<td>isosorbide dinitrate 5 mg tablet: sublingual, 100</td>
<td>4@ 23.89</td>
<td>MK</td>
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<tr>
<td>1588N</td>
<td>ketoprofen 100 mg suppository, 20</td>
<td>20@ 9.44</td>
<td>SW</td>
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<tr>
<td>5139L</td>
<td>lactate sodium 0.322% (3.22 g/1000 mL) + sodium chloride 0.6% (6 g/1000 mL) + potassium chloride 0.04% (400 mg/1000 mL) + calcium chloride dihydrate 0.027% (270 mg/1000 mL) injection, 1 x 1000 mL bag</td>
<td>1@ 1.82</td>
<td>BX</td>
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<tr>
<td>5387M</td>
<td>LACTULOSE Mixture 3.34 g per 5 mL, 500 mL, 1</td>
<td>1@ 3.94</td>
<td>GA, QA</td>
</tr>
<tr>
<td>5387M</td>
<td>LACTULOSE Mixture 3.34 g per 5 mL, 500 mL, 1</td>
<td>1@ 4.83</td>
<td>AF</td>
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<tr>
<td>5388N</td>
<td>lactopine 250 mg tablet, 70</td>
<td>70@ 1690.52</td>
<td>GK</td>
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<tr>
<td>8798C</td>
<td>levodopa 100 mg + carbidopa anhydrous 25 mg + entacapone 200 mg tablet, 100</td>
<td>100@ 167.75</td>
<td>NV</td>
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<tr>
<td>8799D</td>
<td>levodopa 125 mg + carbidopa anhydrous 31.25 mg + entacapone 200 mg tablet, 100</td>
<td>100@ 173.77</td>
<td>NV</td>
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<td>9292C</td>
<td>levodopa 150 mg + carbidopa anhydrous 37.5 mg + entacapone 200 mg tablet, 100</td>
<td>100@ 182.77</td>
<td>NV</td>
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<tr>
<td>8970D</td>
<td>levodopa 100 mg + carbidopa anhydrous 25 mg + entacapone 200 mg tablet, 100</td>
<td>100@ 152.73</td>
<td>NV</td>
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<td>8753Q</td>
<td>mesalazine 1 g/100 mL enema, 7 x 100 mL</td>
<td>1@ 82.45</td>
<td>FP</td>
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<tr>
<td>8768L</td>
<td>mesalazine 1 g/application enema, 14 applications</td>
<td>1@ 82.45</td>
<td>OA</td>
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<tr>
<td>5389P</td>
<td>macrogol-3350 13.12 g + sodium chloride 350.7 mg + potassium chloride 46.6 mg/25 mL oral liquid, 500 mL</td>
<td>1@ 14.13</td>
<td>AE, GN, HM, NE, TX</td>
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<td>5390Q</td>
<td>macrogol-3350 1 g/g oral liquid: powder for, 30 x 17 g sachets</td>
<td>1@ 14.13</td>
<td>AE, GN, HM, NE, TX</td>
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<td>5426N</td>
<td>macrogol-3350 1 g/g oral liquid: powder for, 510 g</td>
<td>1@ 14.13</td>
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<td>5427F</td>
<td>mercaptopurine 50 mg tablet, 25</td>
<td>25@ 65.09</td>
<td>AS</td>
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<td>8753Q</td>
<td>mesalazine 1 g/100 mL enema, 7 x 100 mL</td>
<td>1@ 82.45</td>
<td>FP</td>
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<td>8768L</td>
<td>mesalazine 1 g/application enema, 14 applications</td>
<td>1@ 82.45</td>
<td>OA</td>
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<tr>
<td>8616L</td>
<td>mesalazine 2 g/60 mL enema, 7 x 60 mL</td>
<td>1@ 82.45</td>
<td>OA</td>
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<td>8617M</td>
<td>mesalazine 4 g/60 mL enema, 7 x 60 mL</td>
<td>1@ 109.87</td>
<td>OA</td>
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<tr>
<td>8598M</td>
<td>mesalazine 500 mg granules, 100 x 500 mg sachets</td>
<td>100@ 145.51</td>
<td>OA</td>
</tr>
<tr>
<td>8731M</td>
<td>mesalazine 500 mg tablet: enteric, 100 tables</td>
<td>100@ 145.51</td>
<td>OA</td>
</tr>
<tr>
<td>2214M</td>
<td>mesalazine 500 mg tablet: modified release, 100 tablets</td>
<td>100@ 145.51</td>
<td>OA</td>
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<tr>
<td>1818Q</td>
<td>METHOTREXATE Injection 50 mg in 2 mL, 1</td>
<td>1@ 3.00</td>
<td>GN</td>
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<td>5423K</td>
<td>methylnaltrexone bromide 12 mg/0.6 mL injection, 1 x 0.6 mL vial</td>
<td>1@ 41.39</td>
<td>LM</td>
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<td>2277W</td>
<td>metronidazole 500 mg/100 mL (0.5%) injection, 5 x 100 mL bags</td>
<td>5@ 7.42</td>
<td>AE</td>
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<td>2298Y</td>
<td>milk powder lactose free formula oral liquid: powder for, 900 g</td>
<td>1@ 21.29</td>
<td>AS</td>
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<td>2975N</td>
<td>milk powder lactose free formula predigested oral liquid: powder for, 900 g</td>
<td>1@ 17.80</td>
<td>NU</td>
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<td>2989H</td>
<td>milk powder lactose modified predigested oral liquid: powder for, 900 g</td>
<td>1@ 17.80</td>
<td>NU</td>
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<td>2357C</td>
<td>milk powder synthetic low calcium oral liquid: powder for, 400 g</td>
<td>1@ 46.87</td>
<td>SB</td>
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<td>3092R</td>
<td>milk protein and fat formula with vitamins and minerals carbohydrate free oral liquid: powder for, 225 g</td>
<td>1@ 26.75</td>
<td>SB</td>
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<td>Code</td>
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<td>8816B</td>
<td>modafinil 100 mg tablet, 60</td>
<td>60@ 170.28</td>
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<td>1836P</td>
<td>mycophenolate Capsule 250 mg, 50</td>
<td>50@ 65.88</td>
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<td>8649F</td>
<td>mycophenolate mofetil 250 mg capsule, 100</td>
<td>100@ 131.76</td>
<td>CR, RO, SZ, TX</td>
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<td>mycophenolate mofetil 500 mg tablet, 50</td>
<td>50@ 131.76</td>
<td>AF, CR, RO, SZ, TX</td>
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<td>2192J</td>
<td>naloxone hydrochloride 400 microgram/mL injection, 1 x 1 mL syringe</td>
<td>1@ 19.68</td>
<td>UC</td>
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<tr>
<td>2196N</td>
<td>naloxone hydrochloride 400 microgram/mL injection, 1 x 1 mL syringe</td>
<td>1@ 19.68</td>
<td>UC</td>
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<td>1674D</td>
<td>naproxen 250 mg tablet, 50</td>
<td>50@ 3.46</td>
<td>AF</td>
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<td>1674D</td>
<td>naproxen 250 mg tablet, 50</td>
<td>50@ 4.58</td>
<td>RO</td>
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<td>5176K</td>
<td>naproxen 250 mg tablet, 50</td>
<td>50@ 3.46</td>
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<td>5176K</td>
<td>naproxen 250 mg tablet, 50</td>
<td>50@ 4.58</td>
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<td>naproxen 250 mg tablet, 50</td>
<td>50@ 3.46</td>
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<td>5349M</td>
<td>naproxen 250 mg tablet, 50</td>
<td>50@ 3.46</td>
<td>AF</td>
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<tr>
<td>8298R</td>
<td>naratriptan 2.5 mg tablet, 2</td>
<td>2@ 11.13</td>
<td>AS</td>
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<tr>
<td>9734H</td>
<td>nevirapine 200 mg capsule, 200</td>
<td>2@ 11.13</td>
<td>AS</td>
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<td>9316H</td>
<td>nebivolol 1.25 mg tablet, 28</td>
<td>28@ 22.10</td>
<td>FK</td>
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<td>2732T</td>
<td>nitrazepam 5 mg tablet, 25</td>
<td>25@ 1.85</td>
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<td>2732T</td>
<td>nitrazepam 5 mg capsule, 25</td>
<td>25@ 3.31</td>
<td>VT</td>
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<td>5359C</td>
<td>nitrazepam 5 mg capsule, 25</td>
<td>25@ 3.31</td>
<td>VT</td>
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<td>25@ 1.85</td>
<td>AF</td>
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<td>nitrazepam 5 mg capsule, 25</td>
<td>25@ 1.85</td>
<td>AF</td>
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<td>5360D</td>
<td>nitrazepam 5 mg capsule, 25</td>
<td>25@ 3.31</td>
<td>VT</td>
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<tr>
<td>1698J</td>
<td>nystatin 100 000 international units/g cream, 15 g</td>
<td>1@ 6.07</td>
<td>FM</td>
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<td>5567B</td>
<td>ofloxacin 0.3% (3 mg/mL) eye drops, 5 mL</td>
<td>1@ 14.44</td>
<td>AG</td>
</tr>
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<td>8383F</td>
<td>ofloxacin 0.3% (3 mg/mL) eye drops, 5 mL</td>
<td>1@ 14.44</td>
<td>AG</td>
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<tr>
<td>9294E</td>
<td>olanzapine 40 mg injection: modified release [1 x 200 mg vial]</td>
<td>1@ 246.68</td>
<td>LY</td>
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<td>9295F</td>
<td>olanzapine 40 mg injection: modified release [1 x 200 mg vial]</td>
<td>1@ 401.42</td>
<td>LY</td>
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<tr>
<td>3134Y</td>
<td>oxazepam 15 mg tablet, 25</td>
<td>25@ 3.92</td>
<td>QA</td>
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<td>3134Y</td>
<td>oxazepam 15 mg tablet, 25</td>
<td>25@ 1.24</td>
<td>AF</td>
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<td>5371Q</td>
<td>oxazepam 15 mg tablet, 25</td>
<td>25@ 1.24</td>
<td>AF</td>
</tr>
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<td>5371Q</td>
<td>oxazepam 15 mg tablet, 25</td>
<td>25@ 3.92</td>
<td>QA</td>
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<td>5373T</td>
<td>oxazepam 15 mg tablet, 25</td>
<td>25@ 3.92</td>
<td>QA</td>
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<td>5373T</td>
<td>oxazepam 15 mg tablet, 25</td>
<td>25@ 1.24</td>
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<td>3135B</td>
<td>oxazepam 30 mg tablet, 25</td>
<td>25@ 3.92</td>
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<td>25@ 1.24</td>
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<td>oxazepam 30 mg tablet, 25</td>
<td>25@ 3.92</td>
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<td>5374W</td>
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<td>25@ 3.92</td>
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<td>5374W</td>
<td>oxazepam 30 mg tablet, 25</td>
<td>25@ 1.24</td>
<td>AF, FM, TX</td>
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<td>8588B</td>
<td>oxcarbazepine 60 mg/mL oral liquid, 250 mL</td>
<td>1@ 65.85</td>
<td>NV</td>
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<td>8461H</td>
<td>pamidronate disodium 15 mg/5 mL injection, 1 x 5 mL vial</td>
<td>1@ 27.01</td>
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<td>8462J</td>
<td>pamidronate disodium 30 mg/10 mL injection, 1 x 10 mL vial</td>
<td>1@ 54.01</td>
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<td>pancreatic extract 10 000 international units capsule: modified release, 100 capsules</td>
<td>100@ 35.45</td>
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<td>100@ 70.66</td>
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<td>100@ 111.77</td>
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<td>100@ 111.77</td>
<td>AB</td>
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<td>5453B</td>
<td>pancreatic extract 5000 international units/100 mg granules: enteric-coated, 20 g</td>
<td>1@ 45.12</td>
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<td>5454C</td>
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<td>1@ 45.12</td>
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<td>8366H</td>
<td>pancreatic extract 5000 units capsule, 100</td>
<td>100@ 65.74</td>
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<td>pancreatic extract 5000 units capsule, 100</td>
<td>100@ 65.74</td>
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<td>5319Y</td>
<td>paracetamol 500 mg suppository, 24</td>
<td>1@ 19.51</td>
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<td>1@ 19.51</td>
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<td>FM, GN, GQ, SW, SZ, TX</td>
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<td>paracetamol 665 mg tablet: modified release, 96 tablets</td>
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<td>5344G</td>
<td></td>
<td>96@ 5.11</td>
<td>GC</td>
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<td>8814X</td>
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<td>96@ 5.11</td>
<td>GC</td>
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<td>2167C</td>
<td>paraffin + retinyl palmitate 138 microgram/g (equivalent to 250 units/g vitamin A)</td>
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<td>2202X</td>
<td></td>
<td>1@ 7.41</td>
<td>AE</td>
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<td>2222Y</td>
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<td>paraffin 1 g/g eye ointment, 3.5 g</td>
<td>1@ 8.68</td>
<td>AQ</td>
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<td>1754H</td>
<td>paraffin 1 g/g eye ointment, 3.5 g</td>
<td>1@ 7.41</td>
<td>IQ</td>
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<tr>
<td>5523Q</td>
<td></td>
<td>1@ 8.68</td>
<td>AQ</td>
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<td>5523Q</td>
<td></td>
<td>1@ 7.41</td>
<td>IQ</td>
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<td>9217D</td>
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<td>1@ 7.41</td>
<td>IQ</td>
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<td>1@ 8.68</td>
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<td>1166J</td>
<td>phenoxybenzamine hydrochloride 10 mg capsule, 30</td>
<td>1@ 66.16</td>
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<td>5024K</td>
<td>phenoxybenzylpenicillin 125 mg/5 mL oral liquid: powder for, 100 mL</td>
<td>1@ 3.88</td>
<td>AE</td>
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<td>8976K</td>
<td></td>
<td>1@ 3.88</td>
<td>AE</td>
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<td>5012T</td>
<td>phenoxybenzylpenicillin 150 mg/5 mL oral liquid, 100 mL</td>
<td>1@ 8.54</td>
<td>QA</td>
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<td>5012T</td>
<td>phenoxybenzylpenicillin 150 mg/5 mL oral liquid, 100 mL</td>
<td>1@ 7.59</td>
<td>FM</td>
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<td></td>
<td>1@ 8.54</td>
<td>QA</td>
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<td>9143F</td>
<td></td>
<td>1@ 7.59</td>
<td>FM</td>
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<td>5029Q</td>
<td>phenoxybenzylpenicillin 250 mg/5 mL oral liquid: powder for, 100 mL</td>
<td>1@ 5.16</td>
<td>AE</td>
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<tr>
<td>8977L</td>
<td></td>
<td>1@ 5.16</td>
<td>AE</td>
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<td>1703P</td>
<td>phenoxybenzylpenicillin 250 mg tablet, 25</td>
<td>25@ 2.45</td>
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<td></td>
<td>25@ 2.45</td>
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<td>25@ 3.62</td>
<td>QA</td>
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<td>3361X</td>
<td></td>
<td>25@ 3.62</td>
<td>QA</td>
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<td>9384X</td>
<td>phenylalanine with carbohydrate containing 50 mg phenylalanine oral liquid: powder for, 30 x 4 g sachets</td>
<td>1@ 127.40</td>
<td>VF</td>
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<tr>
<td>5560P</td>
<td>polyethylene glycol-400 0.25% eye drops, 20 x 0.4 mL unit doses</td>
<td>1@ 6.59</td>
<td>AO</td>
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<tr>
<td>9493P</td>
<td></td>
<td>1@ 6.59</td>
<td>AO</td>
</tr>
<tr>
<td>5532E</td>
<td>polyethylene glycol-400 0.4% + propylene glycol 0.3% eye drops, 28 x 0.8 mL unit doses</td>
<td>1@ 13.83</td>
<td>AQ</td>
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<tr>
<td>9170P</td>
<td>polylactic acid 150 mg injection, 1 x 150 mg vial</td>
<td>1@ 13.83</td>
<td>AQ</td>
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<tr>
<td>9475Q</td>
<td></td>
<td>1@ 220.02</td>
<td>SW</td>
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<td>9476R</td>
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<td>1@ 220.02</td>
<td>SW</td>
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<tr>
<td>2642C</td>
<td>potassium chloride 600 mg (8 mmol potassium) tablet: modified release, 100 tablets</td>
<td>100@ 3.23</td>
<td>NM</td>
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<td>2642C</td>
<td>potassium chloride 600 mg (8 mmol potassium) tablet: modified release, 100 tablets</td>
<td>100@ 4.70</td>
<td>NV</td>
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<td>1920C</td>
<td>prednisolone (as sodium phosphate) 20 mg/100 mL enema, 7 x 100 mL</td>
<td>7@ 51.23</td>
<td>QA</td>
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<td>2554K</td>
<td>prednisolone (as sodium phosphate) 5 mg suppository, 10</td>
<td>1@ 11.76</td>
<td>QA</td>
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<td>1948M</td>
<td>promethazine hydrochloride 50 mg/2 mL injection, 5 x 2 mL ampoules</td>
<td>5@ 11.91</td>
<td>HH</td>
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<tr>
<td>3374N</td>
<td></td>
<td>5@ 11.91</td>
<td>HH</td>
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<td>1953T</td>
<td>propantheline hydrochloride 15 mg tablet, 100</td>
<td>100@ 10.02</td>
<td>QA</td>
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<td>1955X</td>
<td>propylthiouracil 50 mg tablet, 100</td>
<td>100@ 21.61</td>
<td>PL</td>
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<td>2676W</td>
<td>protein hydrolysate formula with medium chain triglycerides oral liquid: powder for, 400 g</td>
<td>1@ 20.69</td>
<td>NT</td>
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<td>8259Q</td>
<td>protein hydrolysate formula with medium chain triglycerides oral liquid: powder for, 450 g</td>
<td>1@ 12.93</td>
<td>NU</td>
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<td>2608G</td>
<td>pyridostigmine bromide 180 mg tablet: modified release, 50 tablets</td>
<td>50@ 71.40</td>
<td>VT</td>
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<td>2724J</td>
<td></td>
<td>50@ 8.29</td>
<td>VT</td>
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<td>8162N</td>
<td>ranitidine 150 mg/10 mL oral liquid, 300 mL</td>
<td>1@ 9.05</td>
<td>AS</td>
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<td>1937Y</td>
<td>ranitidine 150 mg tablet: effervescent, 30</td>
<td>30@ 3.25</td>
<td>AS</td>
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<tr>
<td>8790P</td>
<td>risperidone 1 mg tablet: orally disintegrating, 28</td>
<td>28@ 10.05</td>
<td>JC</td>
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<td>8792R</td>
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<td>28@ 10.05</td>
<td>JC</td>
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<td>8780D</td>
<td>risperidone 25 mg injection: modified release [1 x 25 mg vial] (&amp;) inert substance diluent [1 x 2 mL syringe], 1 pack</td>
<td>1@ 135.34</td>
<td>JC</td>
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<tr>
<td>8794W</td>
<td>risperidone 2 mg tablet: orally disintegrating, 28</td>
<td>28@ 19.81</td>
<td>JC</td>
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<tr>
<td>9080X</td>
<td></td>
<td>28@ 19.81</td>
<td>JC</td>
</tr>
<tr>
<td>8781E</td>
<td>risperidone 37.5 mg injection: modified release [1 x 37.5 mg vial] (&amp;) inert substance diluent [1 x 2 mL syringe], 1 pack</td>
<td>1@ 173.51</td>
<td>JC</td>
</tr>
<tr>
<td>9075P</td>
<td>risperidone 3 mg tablet: orally disintegrating, 28</td>
<td>28@ 28.69</td>
<td>JC</td>
</tr>
<tr>
<td>9076Q</td>
<td>risperidone 4 mg tablet: orally disintegrating, 28</td>
<td>28@ 38.24</td>
<td>JC</td>
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<td>1842Y</td>
<td>risperidone 500 microgram tablet, 20</td>
<td>20@ 2.99</td>
<td>JC, TX</td>
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<tr>
<td>Code</td>
<td>Name, Form/Strength</td>
<td>Pack and Price</td>
<td>Manufacturer</td>
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<td>1846E</td>
<td>risperidone 500 microgram tablet: orally disintegrating, 28</td>
<td>20@ 2.99</td>
<td>JC, TX</td>
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<td>8788M</td>
<td>risperidone 50 mg injection: modified release [1 x 50 mg vial] (&amp;) inert substance diluent [1 x 2 mL syringe], 1 pack</td>
<td>1@ 211.28</td>
<td>JC</td>
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<tr>
<td>8870W</td>
<td>salbutamol 100 microgram/actuation inhalation: pressurised, 200</td>
<td>1@ 5.20</td>
<td>GK</td>
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<td>8288F</td>
<td>salbutamol 2.5 mg/2.5 mL inhalation: solution, 30 x 2.5 mL ampoules</td>
<td>1@ 4.84</td>
<td>AF, CR, GN, GX, QA, SZ, TX</td>
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<td>8782F</td>
<td>salbutamol 5 mg/2.5 mL inhalation: solution, 30 x 2.5 mL ampoules</td>
<td>1@ 5.42</td>
<td>GK</td>
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<tr>
<td>9313E</td>
<td>sodium chloride 0.18% (1.8 g/1000 mL) + glucose 4% (40 g/1000 mL) injection, 1 x 1000 mL bag</td>
<td>1@ 3.42</td>
<td>BX</td>
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<tr>
<td>9209Q</td>
<td>sodium chloride 0.225% (1.125 g/500 mL) + glucose 3.75% (18.75 g/500 mL) injection, 1 x 500 mL bag</td>
<td>1@ 4.47</td>
<td>BX</td>
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<tr>
<td>9215L</td>
<td>sodium chloride 0.5% (2.25 g/500 mL) + glucose 2.5% (12.5 g/500 mL) injection, 1 x 500 mL bag</td>
<td>1@ 4.47</td>
<td>BX</td>
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<tr>
<td>9216M</td>
<td>sodium chloride 0.9% (9 g/1000 mL) injection, 1 x 1000 mL bag</td>
<td>1@ 1.69</td>
<td>BX</td>
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<tr>
<td>9226Y</td>
<td>sodium chloride 3% (30 g/1000 mL) injection, 1 x 1000 mL bag</td>
<td>1@ 2.56</td>
<td>BX</td>
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<td>9243J</td>
<td>sodium chloride 0.3% (9 g/1000 mL) injection, 1 x 1000 mL bag</td>
<td>1@ 2.56</td>
<td>BX</td>
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<tr>
<td>3199J</td>
<td>sodium chloride 8.6 g/1000 mL + potassium chloride 300 mg/1000 mL + calcium chloride dihydrate 330 mg/1000 mL injection, 1 x 1000 mL bag</td>
<td>1@ 7.77</td>
<td>BX</td>
</tr>
<tr>
<td>3199F</td>
<td>sodium chloride 8.6 g/1000 mL + potassium chloride 300 mg/1000 mL + calcium chloride dihydrate 330 mg/1000 mL injection, 1 x 1000 mL bag</td>
<td>1@ 7.77</td>
<td>BX</td>
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<td>9380Q</td>
<td>saofenib 200 mg tablet, 60</td>
<td>60@ 3225.33</td>
<td>BN</td>
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<td>9209C</td>
<td>sorbitol 3.125 g/5 mL + citrate sodium dihydrate 450 mg/5 mL + lauryl sulfoacetate sodium 45 mg/5 mL enema, 12 x 5 mL</td>
<td>1@ 12.93</td>
<td>AE, JT</td>
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<td>9321N</td>
<td>soy lecithin 1% (10 mg/mL) + tocopherols 0.002% (20 microgram/mL) + vitamin A palmate 0.025% (250 microgram/mL) eye spray, 100 actuations</td>
<td>1@ 14.82</td>
<td>RB</td>
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<td>9448G</td>
<td>soy protein and fat formula with vitamins and minerals carbohydrate free oral liquid, 1 x 384 mL can</td>
<td>1@ 14.82</td>
<td>RB</td>
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<td>8577K</td>
<td>sulfasalazine 500 mg tablet, 100</td>
<td>1@ 5.53</td>
<td>AB</td>
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<td>2093E</td>
<td>SULFASALAZINE Tablet 500 mg (enteric coated), 100</td>
<td>100@ 21.93</td>
<td>PF</td>
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<td>2098P</td>
<td>SULFASALAZINE Tablet 500 mg (enteric coated), 100</td>
<td>100@ 21.93</td>
<td>PF</td>
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<td>SULFASALAZINE Tablet 500 mg (enteric coated), 100</td>
<td>100@ 25.16</td>
<td>PF</td>
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<td>SULFASALAZINE Tablet 500 mg (enteric coated), 100</td>
<td>100@ 23.92</td>
<td>FZ</td>
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<td>9209Q</td>
<td>SUMATRIPTAN Tablet (fast disintegrating) 50 mg (as succinate), 2</td>
<td>2@ 7.26</td>
<td>AS</td>
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<td>8885P</td>
<td>SUMATRIPTAN Tablet 50 mg (as succinate), 2</td>
<td>2@ 5.76</td>
<td>AF, AS, CH, QA, SZ, TW, TX</td>
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<td>2@ 7.26</td>
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<td>1880Y</td>
<td>tamoxifen 20 mg tablet, 30</td>
<td>30@ 16.23</td>
<td>AP</td>
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<td>temazepam 10 mg tablet, 25</td>
<td>25@ 1.04</td>
<td>AF, FM, TX</td>
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<td>temazepam 10 mg tablet, 25</td>
<td>25@ 3.09</td>
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<td>5375X</td>
<td>temozolomide 100 mg capsule, 5</td>
<td>25@ 1.04</td>
<td>AF, FM, TX</td>
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<td>5375X</td>
<td>temozolomide 100 mg capsule, 5</td>
<td>25@ 3.09</td>
<td>QA</td>
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<td>25@ 3.09</td>
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<td>temozolomide 100 mg capsule, 5</td>
<td>25@ 1.04</td>
<td>AF, FM, TX</td>
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<td>8821G</td>
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<td>5@ 497.62</td>
<td>AF, EA, GN, MK, ON, QA</td>
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<td>9361Q</td>
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<td>5@ 674.36</td>
<td>AF, EA, GN, MK, ON, QA</td>
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<td>temozolomide 180 mg capsule, 5</td>
<td>5@ 841.94</td>
<td>GN, MK, ON</td>
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<td>8820F</td>
<td>temozolomide 20 mg capsule, 5</td>
<td>5@ 120.24</td>
<td>GN, MK, ON</td>
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<td>8819E</td>
<td>temozolomide 5 mg capsule, 5</td>
<td>5@ 42.75</td>
<td>QA</td>
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<tr>
<td>9160D</td>
<td>terbinafine hydrochloride 1% cream, 15 g</td>
<td>1@ 15.47</td>
<td>NC</td>
</tr>
<tr>
<td>2817G</td>
<td>terbutaline sulfate 500 microgram/actuation inhalation: powder, 100 actuations</td>
<td>1@ 5.72</td>
<td>AP</td>
</tr>
<tr>
<td>2832C</td>
<td>tetracosactrin 1 mg/mL injection: modified release, 1 x 1 mL ampoule</td>
<td>1@ 12.97</td>
<td>NV</td>
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<tr>
<td>8222R</td>
<td>tiagabine 10 mg tablet, 50</td>
<td>50@ 66.21</td>
<td>QA</td>
</tr>
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<td>8223T</td>
<td>tiagabine 15 mg tablet, 50</td>
<td>50@ 95.24</td>
<td>OA</td>
</tr>
<tr>
<td>8221Q</td>
<td>tiagabine 5 mg tablet, 50</td>
<td>50@ 33.10</td>
<td>OA</td>
</tr>
<tr>
<td>10113G</td>
<td>ticarcillin 3 g + clavulanic acid 100 mg injection, 1 x 3.1 g vial</td>
<td>1@ 15.70</td>
<td>AS</td>
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<td>10125X</td>
<td>ticarcillin 3 g + clavulanic acid 100 mg injection, 1 x 3.1 g vial</td>
<td>1@ 15.70</td>
<td>AS</td>
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<tr>
<td>1356J</td>
<td>tobramycin 80 mg/2 mL injection, 5 x 2 mL vials</td>
<td>5@ 29.30</td>
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<tr>
<td>8872Y</td>
<td>tobramycin Injection 80 mg (base) in 2 mL (without preservative), 5</td>
<td>5@ 29.30</td>
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<tr>
<td>2117K</td>
<td>trimacinolone acetate 0.02% (200 microgram/g) cream, 100 g</td>
<td>1@ 3.99</td>
<td>FM</td>
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<tr>
<td>2117K</td>
<td>trimacinolone acetate 0.02% (200 microgram/g) cream, 100 g</td>
<td>1@ 5.88</td>
<td>QA</td>
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<tr>
<td>2118L</td>
<td>trimacinolone acetate 0.02% (200 microgram/g) ointment, 100 g</td>
<td>1@ 3.99</td>
<td>FM</td>
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<tr>
<td>2118L</td>
<td>trimacinolone acetate 0.02% (200 microgram/g) ointment, 100 g</td>
<td>1@ 5.88</td>
<td>QA</td>
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<tr>
<td>10037G</td>
<td>triglycerides long chain oral liquid, 18 x 250 mL cartons</td>
<td>1@ 146.70</td>
<td>VF</td>
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<tr>
<td>9308X</td>
<td>triglycerides long chain with glucose polymer oral liquid, 18 x 250 mL cans</td>
<td>1@ 55.56</td>
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<td>9309Y</td>
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<tr>
<td>3136C</td>
<td>triglycerides medium chain and long chain with glucose polymer oral liquid: powder for, 400 g</td>
<td>1@ 36.14</td>
<td>SB</td>
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<tr>
<td>9383W</td>
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<td>1@ 61.80</td>
<td>VF</td>
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<td>1938B</td>
<td>triglycerides medium chain formula oral liquid: powder for, 400 g</td>
<td>1@ 54.55</td>
<td>VF</td>
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<tr>
<td>847BF</td>
<td>triglycerides medium chain oil: oral, 500 mL</td>
<td>1@ 51.86</td>
<td>SB</td>
</tr>
<tr>
<td>3128P</td>
<td>triglycerides medium chain oil: oral, 500 mL</td>
<td>1@ 22.98</td>
<td>SB</td>
</tr>
<tr>
<td>10049X</td>
<td>triglycerides medium chain oral liquid, 18 x 250 mL cartons</td>
<td>1@ 188.55</td>
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<tr>
<td>9327X</td>
<td>triglycerides medium chain oral liquid, 1 x 250 mL bottle</td>
<td>1@ 26.00</td>
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<td>2666H</td>
<td>trimethoprim 300 mg tablet, 7</td>
<td>7@ 3.85</td>
<td>QA</td>
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<td>2666H</td>
<td>trimethoprim 300 mg tablet, 7</td>
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<td>9165J</td>
<td>tyrosine with carbohydrate containing 1 g tyrosine oral liquid: powder for, 30 x 4 sachets</td>
<td>1@ 127.40</td>
<td>VF</td>
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<td>8448P</td>
<td>ursodeoxycholic acid 250 mg capsule, 100</td>
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<td>OA</td>
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<td>8133C</td>
<td>valaciclovir 500 mg tablet, 10</td>
<td>10@ 21.88</td>
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<td>9434M</td>
<td>valine with carbohydrate containing 1 g valine oral liquid: powder for, 30 x 4 g sachets</td>
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<td>VF</td>
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<tr>
<td>9135T</td>
<td>valine with carbohydrate containing 50 mg valine oral liquid: powder for, 30 x 4 g sachets</td>
<td>1@ 127.40</td>
<td>VF</td>
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<tr>
<td>2294R</td>
<td>valproate sodium 100 mg tablet, 100</td>
<td>100@ 12.79</td>
<td>SW</td>
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<tr>
<td>2293Q</td>
<td>valproate sodium 200 mg/5 mL oral liquid, 300 mL</td>
<td>1@ 14.25</td>
<td>SW</td>
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<td>2295T</td>
<td>valproate sodium 100 mg tablet, 100</td>
<td>1@ 14.25</td>
<td>SW</td>
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<td>2289L</td>
<td>valproate sodium 200 mg tablet: enteric, 100</td>
<td>100@ 9.35</td>
<td>AF, QA, SZ, WA</td>
</tr>
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<td>2289L</td>
<td>valproate sodium 200 mg tablet: enteric, 100</td>
<td>100@ 10.35</td>
<td>SW</td>
</tr>
<tr>
<td>2290M</td>
<td>valproate sodium 500 mg tablet: enteric, 100</td>
<td>100@ 18.33</td>
<td>AF, QA, SZ, WA</td>
</tr>
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<td>2290M</td>
<td>valproate sodium 500 mg tablet: enteric, 100</td>
<td>100@ 19.33</td>
<td>SW</td>
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<td>3113W</td>
<td>vancomycin 125 mg capsule, 20</td>
<td>20@ 112.92</td>
<td>AS</td>
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<td>2270L</td>
<td>vancomycin 1 g injection, 1 x 1 g vial</td>
<td>1@ 4.00</td>
<td>AF, GN, HH, SZ</td>
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<tr>
<td>3114X</td>
<td>vancomycin 250 mg capsule, 20</td>
<td>20@ 216.81</td>
<td>AS</td>
</tr>
<tr>
<td>3130R</td>
<td>vancomycin 500 mg injection, 1 x 500 mg vial</td>
<td>1@ 1.99</td>
<td>AF, HH, SZ</td>
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### APPLY WASTAGE FACTOR IN CALCULATING BROKEN QUANTITY PRICES

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Form/Strength</th>
<th>Pack and Price</th>
<th>Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>3131T</td>
<td>1@ varenicline 1 mg tablet, 56</td>
<td>1.99</td>
<td>AF, AS, HH, SZ</td>
</tr>
<tr>
<td>3323X</td>
<td>1@ vinorelbine 20 mg capsule, 1</td>
<td>1.99</td>
<td>AF, AS, HH, SZ</td>
</tr>
<tr>
<td>9129L</td>
<td>56@ vinorelbine 30 mg capsule, 1</td>
<td>112.64</td>
<td>PF</td>
</tr>
<tr>
<td>9009E</td>
<td>1@ vinorelbine 20 mg capsule, 1</td>
<td>78.64</td>
<td>FB</td>
</tr>
<tr>
<td>9010F</td>
<td>1@ vinorelbine 30 mg capsule, 1</td>
<td>117.55</td>
<td>FB</td>
</tr>
<tr>
<td>9328Y</td>
<td>1@ vitamins, minerals and trace elements with carbohydrate oral liquid: powder for, 200 g</td>
<td>64.00</td>
<td>SB</td>
</tr>
<tr>
<td>9382T</td>
<td>1@ whey protein formula supplemented with amino acids, long chain polyunsaturated fatty acids, vitamins and minerals, low in protein, phosphate, potassium and lactose oral liquid: powder for, 10 x 100 g sachets</td>
<td>164.35</td>
<td>VF</td>
</tr>
<tr>
<td>2870C</td>
<td>1@ whey protein formula supplemented with amino acids, long chain polyunsaturated fatty acids, vitamins and minerals, low in protein, phosphate, potassium and lactose oral liquid: powder for, 6 x 400 g cans</td>
<td>394.46</td>
<td>VF</td>
</tr>
<tr>
<td>8587Y</td>
<td>1@ whey protein formula supplemented with amino acids, vitamins and minerals, and low in protein, phosphate, potassium and lactose oral liquid: powder for, 400 g</td>
<td>66.22</td>
<td>SB</td>
</tr>
<tr>
<td>8266C</td>
<td>2@ zolmitriptan 2.5 mg tablet, 2</td>
<td>11.09</td>
<td>AP</td>
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<td>8266C</td>
<td>2@ zolmitriptan 2.5 mg tablet, 2</td>
<td>9.71</td>
<td>QA</td>
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<tr>
<td>9390F</td>
<td>56@ zonisamide 100 mg capsule, 56</td>
<td>43.52</td>
<td>SA</td>
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Section 4

Drug Tariff

Container Prices

Standard Formulae Preparations

Table of Codes, Maximum Quantities, and Number of Repeats for Extemporaneously Prepared Pharmaceutical Benefits
## Drug Tariff

<table>
<thead>
<tr>
<th>Drug</th>
<th>Standard</th>
<th>Recovery Prices</th>
<th>0.1 g/mL</th>
<th>1 g/mL</th>
<th>10 g/mL</th>
<th>100 g/mL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acacia Mucilage (by weight)</td>
<td>APF 15</td>
<td></td>
<td>0.01</td>
<td>0.09</td>
<td>0.70</td>
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<td>Acacia, powdered</td>
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<td>0.02</td>
<td>0.16</td>
<td>1.25</td>
<td>11.07</td>
</tr>
<tr>
<td>Acetic Acid (6 per cent)</td>
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<td>0.02</td>
<td>0.14</td>
<td>1.23</td>
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<td>Acetic Acid (33 per cent)</td>
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<td>0.06</td>
<td>0.46</td>
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<tr>
<td>Acetone (use as additive only)</td>
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<td>0.15</td>
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<tr>
<td>Alum</td>
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<td>0.07</td>
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<tr>
<td>Aluminium Acetate Solution</td>
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<td>0.16</td>
<td>1.29</td>
<td>11.48</td>
</tr>
<tr>
<td>Anise Water Concentrated 1 in 40 (use as additive only)</td>
<td>BP</td>
<td></td>
<td>0.01</td>
<td>0.07</td>
<td>0.55</td>
<td>4.91</td>
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<tr>
<td>Aqueous Cream (for use only as a base combined with active ingredients)</td>
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<td></td>
<td>0.01</td>
<td>0.02</td>
<td>0.19</td>
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<tr>
<td>Ascorbic Acid (for use only as an ingredient of ferrous sulfate mixtures)</td>
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<td>1.89</td>
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<td>Aspirin</td>
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<td>Belladonna Tincture</td>
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<td>Benzoic Acid Compound Ointment</td>
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<td>0.99</td>
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<td>Benzoin Compound Tincture</td>
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<td>0.25</td>
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<tr>
<td>Boric Acid (use as additive only)</td>
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<td>0.11</td>
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<tr>
<td>Boric Acid, Olive Oil and Zinc Oxide Ointment</td>
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<tr>
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<tr>
<td>Cetomacrogol Aqueous Cream (for use only as a base combined with active ingredients)</td>
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<td>0.68</td>
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<tr>
<td></td>
<td></td>
<td>0.1 g/mL</td>
<td>1 g/mL</td>
<td>10 g/mL</td>
<td>100 g/mL</td>
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<td>0.08</td>
<td>0.64</td>
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<td>Chloroform Water Concentrated 1 in 40</td>
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<td>0.26</td>
<td>2.08</td>
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<td>Coal Tar</td>
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<td>1.80</td>
<td>14.36</td>
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<td>0.13</td>
<td>1.05</td>
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<td>48.74</td>
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<td>0.10</td>
<td>0.80</td>
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<td>0.06</td>
<td>0.48</td>
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<tr>
<td>Codeine Phosphate</td>
<td>(may only be prescribed in linctuses, mixtures or mixtures for children)</td>
<td>BP</td>
<td>2.72</td>
<td>21.75</td>
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<td>0.06</td>
<td>0.48</td>
<td>4.27</td>
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<tr>
<td>Ephedrine Hydrochloride</td>
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<td>1.56</td>
<td>12.49</td>
<td>99.90</td>
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<td>Ethanol (90 per cent)</td>
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<td>0.03</td>
<td>0.27</td>
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<td>Ethanol (96 per cent)</td>
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<td>BP</td>
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<td>0.04</td>
<td>0.29</td>
<td>2.54</td>
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<td>Ether Solvent</td>
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<td>BP</td>
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<td>1.34</td>
<td>10.72</td>
<td>95.31</td>
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<tr>
<td>Eucalyptus Oil</td>
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<td>0.14</td>
<td>1.09</td>
<td>9.65</td>
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<tr>
<td>Ferrous Sulfate</td>
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<td>0.16</td>
<td>1.28</td>
<td>10.27</td>
<td>91.25</td>
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<tr>
<td>Formaldehyde Solution</td>
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<td>BP</td>
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<td>0.92</td>
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<td>65.55</td>
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<td>Gentian Alkaline Mixture</td>
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<td>0.52</td>
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<tr>
<td>Glycerol</td>
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<td>0.07</td>
<td>0.59</td>
<td>5.23</td>
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<td>Honey Purified</td>
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# Container Prices

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<td><strong>POISON BOTTLES –</strong></td>
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- **Dispensing Fee for Extemporaneously Prepared Benefits** 8.80
- **Additional Fee for Agreed Price Extemporaneously Prepared Benefits** 1.50
## Standard Formula Preparations

The following list is not intended to indicate in any way which particular formula an approved pharmacist should use in filling a prescription. The prices shown in the column 'Dispensed Price for Max. Qty' are for the ingredients, the container and the dispensing fee. The prices shown in the column 'Maximum Recordable Value for Safety Net' are for the ingredients, the container and the dispensing fee and, where applicable, the additional fee for agreed price benefits.

**KEY TO REFERENCES:**

- **APF**: Australian Pharmaceutical Formulary
- **BP**: British Pharmacopoeia
- **BPC**: British Pharmaceutical Codex
- **QHF**: Queensland Hospital Formulary

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<tr>
<th>Code</th>
<th>Item</th>
<th>Reference</th>
<th>Dispensed Price for Max. Qty</th>
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<td>7502W</td>
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<td>7314Y</td>
<td>Sodium Bicarbonate</td>
<td>APF &amp; BP</td>
<td>10.16</td>
<td>11.66</td>
</tr>
<tr>
<td>7313X</td>
<td>Spirit</td>
<td>APF</td>
<td>9.94</td>
<td>11.44</td>
</tr>
<tr>
<td>7484X</td>
<td>Benzoin and Menthol</td>
<td>APF</td>
<td>21.44</td>
<td>22.94</td>
</tr>
<tr>
<td>7308P</td>
<td>Menthol</td>
<td>APF</td>
<td>12.99</td>
<td>14.49</td>
</tr>
<tr>
<td>7310R</td>
<td>Menthol and Eucalyptus</td>
<td>BP 1980</td>
<td>13.83</td>
<td>15.33</td>
</tr>
<tr>
<td>7530H</td>
<td>Codeine</td>
<td>APF</td>
<td>13.82</td>
<td>15.32</td>
</tr>
<tr>
<td>7709R</td>
<td>Aluminium Acetate Aqueous</td>
<td>APF</td>
<td>12.35</td>
<td>13.85</td>
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<tr>
<td>7604F</td>
<td>Gentian Alkaline</td>
<td>APF</td>
<td>19.05</td>
<td>20.55</td>
</tr>
<tr>
<td>7348R</td>
<td>Kaolin</td>
<td>BPC 1968</td>
<td>24.52</td>
<td>26.02</td>
</tr>
<tr>
<td>7301G</td>
<td>Kaolin and Opium</td>
<td>APF 14</td>
<td>21.97</td>
<td>23.47</td>
</tr>
<tr>
<td>7342K</td>
<td>Magnesium Trisilicate</td>
<td>BPC 1968</td>
<td>18.68</td>
<td>20.18</td>
</tr>
<tr>
<td>7343L</td>
<td>Magnesium Trisilicate and Belladonna</td>
<td>BPC 1968</td>
<td>24.26</td>
<td>25.76</td>
</tr>
<tr>
<td>Code</td>
<td>Item</td>
<td>Reference</td>
<td>Dispensed Price for Max. Qty</td>
<td>Maximum Recordable Value for Safety Net</td>
</tr>
<tr>
<td>-------</td>
<td>-------------------------------------------</td>
<td>-----------</td>
<td>-----------------------------</td>
<td>----------------------------------------</td>
</tr>
<tr>
<td>7457L</td>
<td>Thymol Compound</td>
<td>APF 15</td>
<td>24.39</td>
<td>25.89</td>
</tr>
<tr>
<td>7914M</td>
<td>Benzoic Acid Compound</td>
<td>APF &amp; BP</td>
<td>18.86</td>
<td>20.36</td>
</tr>
<tr>
<td>7902X</td>
<td>Boric Acid, Olive Oil and Zinc Oxide</td>
<td>QHF</td>
<td>16.94</td>
<td>18.44</td>
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<tr>
<td>7926E</td>
<td>Salicylic Acid</td>
<td>APF</td>
<td>19.05</td>
<td>20.55</td>
</tr>
<tr>
<td>7928G</td>
<td>Salicylic Acid (extemporaneous formula)</td>
<td>BP</td>
<td>19.05</td>
<td>20.55</td>
</tr>
<tr>
<td>7945L</td>
<td>Magnesium Trisilicate</td>
<td>BP</td>
<td>33.64</td>
<td>35.14</td>
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---CONTAINER RATES ARE INCLUDED---
### Table of Codes, Maximum Quantities, and Number of Repeats for Extemporaneously Prepared Benefits

<table>
<thead>
<tr>
<th>Code</th>
<th>Preparation</th>
<th>Maximum Quantity</th>
<th>Number of Repeats</th>
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</thead>
<tbody>
<tr>
<td>13Q</td>
<td>Creams</td>
<td>100 g</td>
<td>1</td>
</tr>
<tr>
<td>48M</td>
<td>Dusting Powders</td>
<td>100 g</td>
<td>1</td>
</tr>
<tr>
<td>15T</td>
<td>Ear Drops</td>
<td>15 mL</td>
<td>2</td>
</tr>
<tr>
<td>19B</td>
<td>Eye Drops containing Cocaine Hydrochloride</td>
<td>15 mL</td>
<td>..</td>
</tr>
<tr>
<td>22E</td>
<td>Eye Drops, Other</td>
<td>15 mL</td>
<td>5</td>
</tr>
<tr>
<td>23F</td>
<td>Eye Lotions</td>
<td>200 mL</td>
<td>2</td>
</tr>
<tr>
<td>29M</td>
<td>Inhalations</td>
<td>50 mL</td>
<td>1</td>
</tr>
<tr>
<td>64J</td>
<td>Linctuses containing Codeine Phosphate</td>
<td>100 mL</td>
<td>..</td>
</tr>
<tr>
<td>34T</td>
<td>Linctuses, Other</td>
<td>100 mL</td>
<td>2</td>
</tr>
<tr>
<td>39C</td>
<td>Lotions</td>
<td>200 mL</td>
<td>2</td>
</tr>
<tr>
<td>65K</td>
<td>Mixtures containing Codeine Phosphate</td>
<td>200 mL</td>
<td>..</td>
</tr>
<tr>
<td>40D</td>
<td>Mixtures, Other</td>
<td>200 mL</td>
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<tr>
<td>66L</td>
<td>Mixtures for Children containing Codeine Phosphate</td>
<td>100 mL</td>
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<td>41E</td>
<td>Mixtures for Children, Other</td>
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<td>30N</td>
<td>Mouth Washes</td>
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<tr>
<td>42F</td>
<td>Nasal Instillations</td>
<td>15 mL</td>
<td>2</td>
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<tr>
<td>43G</td>
<td>Ointments, Waxes</td>
<td>100 g</td>
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<tr>
<td>44H</td>
<td>Paints</td>
<td>25 mL</td>
<td>1</td>
</tr>
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<td>63H</td>
<td>Pastes containing Cocaine Hydrochloride</td>
<td>25 g</td>
<td>..</td>
</tr>
<tr>
<td>45J</td>
<td>Pastes, Other</td>
<td>100 g</td>
<td>1</td>
</tr>
<tr>
<td>49N</td>
<td>Powders for Internal Use</td>
<td>100 g</td>
<td>2</td>
</tr>
<tr>
<td>52R</td>
<td>Solutions</td>
<td>200 mL</td>
<td>2</td>
</tr>
</tbody>
</table>

Special Note: Purified Water BP is the minimum requirement for water in all PBS extemporaneous preparations.
The benefits listed in this Schedule may only be prescribed to Department of Veterans' Affairs beneficiaries holding a:

- Repatriation Health Card For All Conditions (gold); or
- Repatriation Health Card For Specific Conditions (white); or
- Repatriation Pharmaceutical Benefits Card (orange);
## BENEFICIARIES' ENTITLEMENT CARDS AND ELIGIBILITY FOR REPATRIATION PHARMACEUTICAL BENEFITS

<table>
<thead>
<tr>
<th><strong>Gold card</strong></th>
<th><img src="Image" alt="Gold card image" /></th>
</tr>
</thead>
<tbody>
<tr>
<td>This card is issued to those veterans of Australia’s defence force, their widows/widowers and dependants entitled to treatment for all medical conditions.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>White card</strong></th>
<th><img src="Image" alt="White card image" /></th>
</tr>
</thead>
<tbody>
<tr>
<td>A White Card is issued to Australian veterans or mariners under the Veterans’ Entitlements Act 1986 with:</td>
<td></td>
</tr>
<tr>
<td>• an accepted war or service-caused injury or disease;</td>
<td></td>
</tr>
<tr>
<td>• malignant cancer (neoplasia) whether war-caused or not;</td>
<td></td>
</tr>
<tr>
<td>• pulmonary tuberculosis whether war-caused or not;</td>
<td></td>
</tr>
<tr>
<td>• post-traumatic stress disorder whether war-caused or not; or</td>
<td></td>
</tr>
<tr>
<td>• anxiety and/or depression whether war-caused or not.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Orange card</strong></th>
<th><img src="Image" alt="Orange card image" /></th>
</tr>
</thead>
<tbody>
<tr>
<td>Orange Repatriation pharmaceutical benefits cards are issued to Commonwealth and allied veterans and mariners who:</td>
<td></td>
</tr>
<tr>
<td>• have qualifying service from World War I or II and</td>
<td></td>
</tr>
<tr>
<td>• are aged 70 or over and</td>
<td></td>
</tr>
<tr>
<td>• have been resident in Australia for 10 years or more.</td>
<td></td>
</tr>
</tbody>
</table>

For more information go to the Department of Veterans’ Affairs website: http://www.dva.gov.au/service_providers/treatment_cards/Pages/index.aspx
RPBS Explanatory Notes

Introduction

The Australian Repatriation System

- The Australian Repatriation system is based primarily on the principle of compensation to veterans and eligible dependants for injury or death related to war service. In certain cases, treatment is also provided for accepted injuries or conditions that are not service-related or have occurred as a result of other than war service.

- Through the Veterans’ Entitlements Act 1986 the Department of Veterans’ Affairs provides programs of compensation, income support and treatment for eligible veterans and their dependants. One of the defined benefits for eligible veterans is the Repatriation Pharmaceutical Benefits Scheme. This range of medications and dressings is more comprehensive than is available through the Pharmaceutical Benefits Scheme.

RPBS prescribing provisions

- Unless otherwise stated, Repatriation Pharmaceutical Benefits Scheme (RPBS) prescriptions must conform with the requirements of Pharmaceutical Benefits Scheme (PBS) prescriptions, as detailed in Section 1 – Explanatory Notes in the Schedule of Pharmaceutical Benefits book. The prescriber shall ensure that a prescription contains the following details:
  - the category of benefit, i.e., RPBS, by placing a cross in the relevant box;
  - the patient’s full name and address;
  - the prescription date;
  - the DVA file number of the patient as evidence of entitlement;
  - in the case of authority prescriptions, the Authority approval number or the four digit streamlined authority code;
  - the item, form, strength, quantity and directions;
  - the number of repeats, if applicable;
  - indicate when brand substitution is not permitted; and
  - the name, signature, the prescriber number and address of the prescriber.

Prior Approval Arrangements

- The prior approval of the Department is required to prescribe the following:
  - ‘Authority required’ items (excluding ‘Authority required (STREAMLINED)’ items) listed in either the PBS or RPBS Schedule;
  - increased quantities and/or repeats of items listed in either the PBS or RPBS Schedule;
  - items listed under section 100 of the National Health Act 1953; and
  - other items not listed in either Schedule (non-Schedule items).

- The above items are to be prescribed on the common PBS/RPBS authority prescription form in accordance with the directions stated in the Explanatory Notes in the Schedule of Pharmaceutical Benefits (See also information regarding dental prescribing and prescribing by optometrists under the RPBS in these Notes.)

- All Authority required prescriptions and requests for non-Schedule items must receive prior approval from the Department. This can be achieved by either:
  - using the Department’s national free call number 1800 552 580; or
  - by mailing the written authority prescription to the Veterans’ Affairs Pharmaceutical Advisory Centre (VAPAC) at the reply paid address shown at the end of these RPBS Explanatory Notes.

Prior approval is not required from DVA to prescribe an Authority required (STREAMLINED) item (except where increased quantities and/or repeats are required). Instead the authority prescription form must include a four digit streamlined authority code.

- Some requests for prior approval (including some non-Schedule items) need to be referred by VAPAC to the Repatriation Pharmaceutical Reference Committee for consideration. In such cases a VAPAC pharmacist will advise the prescriber to submit a request in writing that provides the following information:
  - A current clinical report on the patient’s condition (such as age, co-morbidities, renal, liver failure) and clinical reports including pathology, biochemistry, diagnostic and other investigations if appropriate.
  - Details of past and current therapy for the condition. Include details of PBS, RPBS and non-Schedule items utilised, and the results of those therapies.
  - Details of the proposed treatment regimen. Include intended dose and duration of treatment and objective measures of response.
When the proposed use of the item is outside the TGA-approved indications for use in Australia, provide copies of articles from peer reviewed publications supporting the proposed treatment.

Signed, informed patient consent where the item is to be used for a non-TGA-approved indication.

Requests for prior approval to prescribe a non-Schedule (PBS or RPBS) item that is of the same therapeutic class (ATC level 3) as an item that is listed on the Schedule, will not be approved unless unequivocal clinical evidence is presented to demonstrate that the requested item is essential for effective treatment of the nominated patient.

A pharmacist should not supply an item prescribed on an RPBS Authority Prescription Form unless the form has been approved and stamped by VAPAC, or has been endorsed by the prescriber with a telephone Authority approval number provided by VAPAC. The Department of Human Services will not accept RPBS Authority prescriptions that have not been approved by the Department of Veterans’ Affairs for payment.

**Palliative Care Drugs**

The following medications may be available, or made available in increased quantities or doses under prior approval arrangements for use only in the palliative care of terminal disease:

- clonazepam
- cyclizine
- dexamethasone
- disodium pamidronate
- fentanyl
- glycopyrrolate
- hyoscine butylbromide
- hyoscine hydrobromide
- ketamine
- midazolam
- octreotide

For further information telephone VAPAC on 1800 552 580.

**Dental Prescribing**

Under Department of Veterans’ Affairs arrangements, financial responsibility for pharmaceutical benefits prescribed by a Local Dental Officer (LDO) is limited to treatment to which holders of the following cards are entitled:

- a Gold Repatriation Health Card – For All Conditions; or
- a White Repatriation Health Card – For Specific Conditions; or
- an Orange Repatriation Pharmaceutical Benefits Card.

Where possible the LDO shall prescribe in accordance with the provisions governing dental prescribing under the Pharmaceutical Benefits Scheme (PBS).

Prescriptions for PBS Dental Schedule items for Gold, White and Orange Card holders are to be dispensed at the PBS concessional rate. Claims for payment by the dispensing pharmacist are to be included with other Repatriation prescriptions. The card holder is required to meet the cost of any applicable brand premium.

When a non-PBS Dental Schedule item is prescribed for an eligible card holder, the LDO’s private prescription form should be used. The dispensing pharmacist may charge the patient the full cost of the prescription. The patient may claim a refund for the full cost of a non-Schedule item from the Department if an itemised receipt (not a cash register receipt) and a copy of the prescription are provided.

**Prescribing by optometrists**

Optometrists approved as ‘PBS prescribers’ may write RPBS prescriptions as outlined in Section 1 for medicines listed in Section 2 of the PBS Schedule as pharmaceutical benefits for optometrical use.

Medicines in the optometrist list include non-Authority and Authority required items. Procedures for obtaining VAPAC approval to prescribe ‘Authority required’ optometrist items or increased quantities and/or repeats of optometrist items under the RPBS are the same as indicated under prior approval arrangements above.
The list of medicines for prescribing by optometrists under the RPBS is the same as applies under the PBS. There are no optometrist listings in the RPBS Schedule for prescribing for veterans only. There is no provision for optometrist prescribers to request approval to prescribe items that are not included in the PBS optometrist list (non-Schedule items).

Optometrist PBS/RPBS prescription forms are for use for prescribing non-Authority or Authority required optometrist items under the RPBS with one item per form only.

Provisions governing pricing and payment for RPBS benefits

Introduction

- Unless otherwise stated, the pricing and payment principles and arrangements for approved pharmacists supplying pharmaceutical benefits under the RPBS will be the same as those arrangements applying under the PBS.
- Where a pharmaceutical benefit that is not listed on the PBS or RPBS Schedule is dispensed on an RPBS Authority prescription, a pharmacist will price the benefit and enter the serial number, prescription identifying number and price on the sticker or stamp imprint affixed to the prescription.

Pricing of Schedule Items

- Items supplied under the RPBS from the PBS Schedule, both ready-prepared and extemporaneously-prepared, will be paid on the same basis as benefits supplied under the PBS. Items supplied under the RPBS from the Repatriation Schedule, including wound dressings, will be paid on the basis of the price as given in the Repatriation Pharmaceutical Benefits section (Section 1 – RPBS Schedule, Drugs, Medicines and Dressings) of the Schedule of Pharmaceutical Benefits.

Pricing of Non-Schedule Ready Prepared Items

- Non-Schedule ready-prepared items are to be priced on the basis of the invoiced, GST-exclusive wholesale price to pharmacists plus the appropriate PBS mark-up and the PBS dispensing fee. Where the item price to pharmacists is greater than $100.00, a copy of the invoice pertaining to the supply of that item is to be submitted together with the appropriate copy of the authority prescription as part of the claim for payment.

Pricing of Non-Schedule Extemporaneously Prepared Items

- When an ingredient drug is not listed in the PBS Drug Tariff, the recovery price will be based on the invoiced wholesale price to pharmacists, increased by a mark-up of 100%, calculated in accordance with the directions contained in the pricing instructions for pricing of PBS extemporaneously-prepared benefits in this Schedule. The price paid by the pharmacist for the commercial pack from which the ingredient is used shall be endorsed on the prescription form.

Miscellaneous Pricing Rules

- The price to pharmacists used as the basis of pricing will be the invoiced, GST-exclusive price from the wholesaler.
- If multiple quantities of a manufacturer’s original pack are supplied, the PBS mark-up is applied to the price to pharmacist of each pack and then totalled. The PBS dispensing fee, and the PBS dangerous drug fee if applicable, are then added to the total of the marked-up prices.
- When the quantity prescribed corresponds with the quantity of a manufacturer’s original pack, in no circumstances will the price payable for one pack exceed that payable for multiples or combinations of packs to supply the quantity prescribed.
- The list of ingredient drugs and prices included in the PBS Drug Tariff are common to both the PBS and RPBS. Certain restrictions apply regarding the prescribing and dispensing of some of these ingredient drugs as pharmaceutical benefits, e.g., use as additive only.
- For items prescribed generically, including non-Schedule and wound dressings, the pharmacist should indicate on the prescription the quantity and brand supplied. If prescriptions are not endorsed, the Department will pay the lowest priced acceptable product available.

General

Packaging Material, Postage or Freight

- Payment to a pharmacist for the costs of packaging materials, postage or freight required to supply a pharmaceutical benefit is to be paid by the patient, who may then claim reimbursement from the Department through the provision of a pharmacists itemised receipt.

Payment for Items Supplied at Short Intervals

- For all items dispensed at specific short intervals of time, the Department will pay a separate PBS dispensing fee for each occasion that the drug is supplied and which is acknowledged on receipt by the patient or agent.
- The price payable on the items supplied will be based on the individual dose quantity supplied. Where applicable, a PBS dangerous drug fee and a minimum container charge will be payable for each supply.
Receipts for Patient Charges

- Where a charge is paid by a patient in any of the circumstances of paragraphs 13 or 24, the pharmacist is required to provide a printed receipt to the patient with the details of the items or services provided, the amount paid, date of supply and the patients name and address. The patient may apply for reimbursement from the Department.

Special Patient Contributions

- The Special Patient Contribution for items listed as Special Pharmaceutical Benefits in the PBS Schedule is not payable by veterans entitled to pharmaceutical benefits under the RPBS. Eligible veterans receiving Special Pharmaceutical Benefits under the RPBS are required to pay only the concessional patient contribution and any applicable brand premium. If a Safety Net Entitlement card is held, the veteran should receive a Special Pharmaceutical Benefit free of charge, subject to any brand premium applicable. The Department of Human Services will reimburse the dispensing pharmacist the total dispensed price, less the concessional patient contribution and/or brand premium if applicable.

Therapeutic Group Premiums — Authority Processing

- Items attracting a therapeutic group premium are dual listed. Dispensing pharmacists are therefore required to select the appropriate code for those items that are dual listed as authority and non-authority items, in order to correctly charge the patient and claim from the Department of Human Services. Those authority prescriptions that grant exemption from a therapeutic group premium will have the letters 'TPX' at the beginning of the telephone Authority approval number, or, in the case of a written approval, will be stamped with the words “This prescription does not attract a therapeutic group premium”.

DEPARTMENT OF VETERANS' AFFAIRS

Authority Prescription Applications

Applications for authority to prescribe under the Repatriation Pharmaceutical Benefits Scheme (RPBS) should be sent to the Veterans' Affairs Pharmaceutical Advisory Centre (VAPAC) using the free postal service:

REPLY PAID 9998
VAPAC (Veterans’ Affairs Pharmaceutical Advisory Centre)
Department of Veterans’ Affairs
GPO Box 9998
BRISBANE QLD 4001

For RPBS enquiries and telephone approvals 24 hours a day the Freecall number is:

1800 552 580

Departmental pharmacists answer applications for prior approval for non-Schedule items and Authority application calls.
REPATRIATION SUMMARY OF CHANGES

Alterations

Alteration – Manufacturer's Code

4325P  **Mebendazole**, mebendazole 100 mg tablet, 6 (Vermox)  

From:  BI  
To:  IA
ALIMENTARY TRACT AND METABOLISM ................................................................................................................ 1087
STOMATOLOGICAL PREPARATIONS .................................................................................................................. 1087
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<td>MACROLIDES, LINCOMAMIDES AND STREPTOGRAMINS</td>
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<td>1103</td>
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<td>IMMUNOSUPPRESSANTS</td>
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<td>DRUGS FOR TREATMENT OF BONE DISEASES</td>
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<td>DRUGS AFFECTING BONE STRUCTURE AND MINERALIZATION</td>
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<td>NERVOUS SYSTEM</td>
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<td>NASAL PREPARATIONS</td>
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<td>DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE</td>
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<td>NASAL DECONGESTANTS FOR SYSTEMIC USE</td>
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<td>COUGH AND COLD PREPARATIONS</td>
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Section 1

Drugs, Medicines and Dressings
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<th>Brand Name and Manufacturer</th>
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<tr>
<td>4161B</td>
<td>chlorhexidine gluconate 0.2% (2 mg/mL) mouthwash, 250 mL</td>
<td>‡1 .. ..</td>
<td>12.23</td>
<td>6.00</td>
<td></td>
<td>Plaqacide</td>
<td>OB</td>
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<td>4204G</td>
<td>chlorhexidine gluconate 0.2% (2 mg/mL) mouthwash, 300 mL</td>
<td>‡1 .. ..</td>
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<td>Savacol Mouth and Throat Rinse</td>
<td>OM</td>
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<td>4569L</td>
<td>carmellose sodium 10 mg/mL oral spray, 100 mL</td>
<td>‡1 .. ..</td>
<td>13.49</td>
<td>6.00</td>
<td></td>
<td>Aqua VT</td>
<td>VT</td>
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<tr>
<td>4568K</td>
<td>carmellose sodium 10 mg/mL oral spray, 25 mL</td>
<td>‡1 1 ..</td>
<td>11.64</td>
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<td>VT</td>
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<td>4055K</td>
<td>calcium carbonate 420 mg + glycine 180 mg tablet: chewable, 100</td>
<td>2 5 ..</td>
<td>*23.52</td>
<td>6.00</td>
<td></td>
<td>Titarlac</td>
<td>MM</td>
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<tr>
<td>4118R</td>
<td>aluminium hydroxide with magnesium hydroxide and simethicone</td>
<td>2 5 ..</td>
<td>*22.98</td>
<td>6.00</td>
<td></td>
<td>Mylanta Double Strength</td>
<td>JT</td>
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<tr>
<td>4453J</td>
<td>aluminium hydroxide with magnesium hydroxide and simethicone</td>
<td>2 5 ..</td>
<td>*46.46</td>
<td>6.00</td>
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<td>Mylanta Double Strength</td>
<td>JT</td>
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<tr>
<td>4328T</td>
<td>mebeverine hydrochloride 135 mg tablet, 90</td>
<td>1 .. ..</td>
<td>27.25</td>
<td>6.00</td>
<td></td>
<td>Colese</td>
<td>AF</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>32.43</td>
<td>6.00</td>
<td></td>
<td>Colofac</td>
<td>AB</td>
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<tr>
<td>4279F</td>
<td>hyoscine butylbromide 20 mg/mL injection, 5 x 1 mL ampoules</td>
<td>1 .. ..</td>
<td>24.55</td>
<td>6.00</td>
<td></td>
<td>Buscopan</td>
<td>BY</td>
</tr>
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</tbody>
</table>

### DRUGS FOR ACID RELATED DISORDERS

#### ANTACIDS

**Calcium compounds**

- **Calcium carbonate + Glycine**
  - **Note**
    - For patients with chronic renal failure.
  - 4055K: calcium carbonate 420 mg + glycine 180 mg tablet: chewable, 100

**Combinations and complexes of aluminium, calcium and magnesium compounds**

- 4118R: aluminium hydroxide with magnesium hydroxide and simethicone
  - Mylan Double Strength
- 4453J: aluminium hydroxide with magnesium hydroxide and simethicone
  - Mylan Double Strength

### DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS

#### DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS

**Synthetic anticholinergics, esters with tertiary amino group**

- **Mebverine**
  - 4328T: mebeverine hydrochloride 135 mg tablet, 90
  - a: Colese
  - 32.43: 6.00

**Belladonna and Derivatives, Plain**

- **Belladonna alkaloids, semisynthetic, quaternary ammonium compounds**
  - 4279F: hyoscine butylbromide 20 mg/mL injection, 5 x 1 mL ampoules
  - Buscopan

### DRUGS FOR CONSTIPATION

#### DRUGS FOR CONSTIPATION

- **Softeners, emollients**
  - 1087: Docusate
### ALIMENTARY TRACT AND METABOLISM

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<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
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<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>4200C</td>
<td>docusate sodium 50 mg tablet, 100</td>
<td>1</td>
<td>2</td>
<td></td>
<td>14.65</td>
<td>6.00</td>
<td>Coloxyl 50 FM</td>
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<tr>
<td>4028B</td>
<td>docusate sodium 50 mg + sennoside B 8 mg tablet, 100</td>
<td>1</td>
<td>2</td>
<td></td>
<td>14.75</td>
<td>6.00</td>
<td>Soflax GN</td>
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<tr>
<td>4198Y</td>
<td>docusate sodium 50 mg + sennosides 11.27 mg tablet, 90</td>
<td>1</td>
<td>2</td>
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<td>13.52</td>
<td>6.00 a</td>
<td>Co-Senna PP</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>17.03</td>
<td>6.00 a</td>
<td>Coloxyl with Senna FM</td>
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<tr>
<td>4455L</td>
<td>sennoside B 7.5 mg tablet, 100</td>
<td>1</td>
<td>1</td>
<td></td>
<td>12.94</td>
<td>6.00 a</td>
<td>Senna-Gen PP</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>14.20</td>
<td>6.00 a</td>
<td>Senokot RC</td>
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### Contact laxatives

**ISPAGHULA HUSK DRY**

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<thead>
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<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
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<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>4285M</td>
<td>ispaghula husk dry 3.5 g oral liquid: powder for, 30 x 3.5 g sachets</td>
<td>‡1</td>
<td>1</td>
<td></td>
<td>17.98</td>
<td>6.00</td>
<td>Fybogel RC</td>
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</table>

**PSYLLIUM HUSK POWDER**

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<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>4422R</td>
<td>psyllium hydrophilic mucilloid oral powder (non-flavoured) 336 g, 1</td>
<td>‡1</td>
<td>1</td>
<td></td>
<td>18.36</td>
<td>6.00</td>
<td>Fibre Health Natural Granular PP</td>
</tr>
<tr>
<td>4419N</td>
<td>psyllium hydrophilic mucilloid oral powder (orange-flavoured, sugar-free) 283 g, 1</td>
<td>‡1</td>
<td>1</td>
<td></td>
<td>22.01</td>
<td>6.00</td>
<td>Metamucil Natural Granular PY</td>
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**RHAMNUS FRANGULA + STERCULIA**

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<th>Name, Restriction, Manner of Administration and Form</th>
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<th>No. of Rpts</th>
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<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>4558X</td>
<td>rhamnus frangula 80 mg/g + sterculia 620 mg/g granules, 500 g</td>
<td>‡1</td>
<td>1</td>
<td></td>
<td>26.71</td>
<td>6.00</td>
<td>Normacol Plus NE</td>
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### Bulk-forming laxatives

**Sorbitol + Citrate + Lauryl Sulfoacetate Sodium**

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<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
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<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>4462W</td>
<td>sorbitol 3.125 g/5 mL + citrate sodium dihydrate 450 mg/5 mL + lauryl sulfoacetate sodium 45 mg/5 mL enema, 4 x 5 mL</td>
<td>‡1</td>
<td>..</td>
<td></td>
<td>12.44</td>
<td>6.00</td>
<td>Micolette AE</td>
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</table>

**Other drugs for constipation**

**GLYCEROL**

*Restricted benefit*

Short-term use when oral laxative therapy has failed or is inappropriate

<table>
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<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
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<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>4246L</td>
<td>glycerol 2.8 g suppository, 12</td>
<td>3</td>
<td>..</td>
<td></td>
<td>*20.74</td>
<td>6.00</td>
<td>Petrus Pharmaceuticals Pty Ltd PP</td>
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## Antiobesity Preparations, Excl. Diet Products

### Antiobesity Preparations, Excl. Diet Products

Peripherally acting antiobesity products

**OIRULSTAT**

*Authority required*

For the treatment of obese patients.

Total treatment will not exceed 12 months from initial application.

Patients are eligible for 1 continuous treatment in a lifetime.

The patient must be receiving, or enrolled to receive, professional dietetic and weight management advice (where this is available).

Initial treatment for patients who meet the following criteria to qualify:

(a) Body Mass Index (BMI) greater than or equal to 35 with no known co-morbidities; or
(b) BMI greater than or equal to 30 with 1 or more of the following co-morbidities:

(i) diabetes;
(ii) ischaemic heart disease;
(iii) psychiatric conditions;
(iv) hypertension.

The prescriber must provide the following:
(a) initial body weight; and
(b) BMI.

Continuing treatment for patients who have previously been issued with an authority prescription for orlistat. After 3 months and up to 6 months following commencement of orlistat treatment, patient’s initial body weight must have been reduced by 2.5 kg or 2.5% (whichever is the lesser).

Continuing treatment for patients who have previously been issued with an authority prescription for orlistat. After 6 months and up to 12 months following commencement of orlistat treatment, patient’s initial body weight must have been reduced by 5 kg or 5% (whichever is the lesser).

Note
The patient should be ideally enrolled in an exercise program and be receiving supplemental vitamins.

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<th>Name, Restriction, Manner of Administration and Form</th>
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**VITAMINS**

**VITAMIN B1, PLAIN AND IN COMBINATION WITH VITAMIN B6 AND B12**

**Vitamin B1, plain**

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<tr>
<th>Code</th>
<th>Name</th>
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<th>No. of Rpts</th>
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<td>4043T</td>
<td>thiamine hydrochloride 100 mg tablet, 100</td>
<td>1 2 ..</td>
<td>10.45</td>
<td>6.00</td>
<td>Betavit PP</td>
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**VITAMIN B-COMPLEX, INCL. COMBINATIONS**

**Vitamin B-complex, plain**

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<th>Brand Name and Manufacturer</th>
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<tr>
<td>4493L</td>
<td>cyanocobalamin 25 microgram/10 mL + iron (as ferric pyrophosphate) 10 mg/10 mL + lysine hydrochloride 300 mg/10 mL + pyridoxine hydrochloride 5 mg/10 mL + thiamine hydrochloride 10 mg/10 mL oral liquid, 200 mL</td>
<td>¥1 2 ..</td>
<td>13.68</td>
<td>6.00</td>
<td>Accomin Adult Tonic PF</td>
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**MINERAL SUPPLEMENTS**

**CALCIUM**

**Calcium**

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<th>Brand Name and Manufacturer</th>
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<td>4094L</td>
<td>CALCIUM Tablet (chewable) 500 mg (as carbonate), 60</td>
<td>4 1 ..</td>
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<td>6.00</td>
<td>Cal-Sup IA</td>
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<tr>
<td>4142B</td>
<td>CALCIUM Tablet 600 mg (as carbonate), 120</td>
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<td>CAL-600 PP</td>
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**Calcium**

**Restricted benefit**

Hyperphosphataemia in chronic renal failure

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<th>Brand Name and Manufacturer</th>
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<td>CALCIUM Tablet (chewable) 500 mg (as carbonate), 60</td>
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<td>Cal-Sup IA</td>
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<td></td>
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<tr>
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<td>CALCIUM Tablet 600 mg (as carbonate), 120</td>
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<td>6.00</td>
<td>CAL-600 PP</td>
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</table>

**Calcium**

**Restricted benefit**

Hypocalcaemia

**Restricted benefit**

Osteoporosis

**Restricted benefit**

Proven calcium malabsorption

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<tr>
<th>Code</th>
<th>Name</th>
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<tr>
<td>4333C</td>
<td>CALCIUM Tablet (chewable) 500 mg (as carbonate), 60</td>
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<td>*18.00</td>
<td>6.00</td>
<td>Cal-Sup IA</td>
<td></td>
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<tr>
<td>4082W</td>
<td>CALCIUM Tablet 600 mg (as carbonate), 120</td>
<td>1 1 ..</td>
<td>14.65</td>
<td>6.00</td>
<td>CAL-600 PP</td>
<td></td>
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### OTHER MINERAL SUPPLEMENTS

**Magnesium**

**Magnesium Aspartate Dihydrate**  
Patients with documented hypomagnesaemia

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<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
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<tr>
<td>4321K</td>
<td>magnesium aspartate dihydrate 500 mg (equivalent to 37.4 mg of magnesium) tablet, 50</td>
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<td>..</td>
<td>14.04</td>
<td>6.00</td>
<td>6.00</td>
<td>Mag-Sup PP</td>
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<tr>
<td></td>
<td>...</td>
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<td>14.73</td>
<td>6.00</td>
<td>6.00</td>
<td>Magmin BB</td>
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## BLOOD AND BLOOD FORMING ORGANS

### ANTITHROMBOTIC AGENTS

**Platelet aggregation inhibitors excl. heparin**

**ASPIRIN**

<table>
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<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
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<td>4078P</td>
<td>aspirin 100 mg capsule: enteric, 84</td>
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<td>1</td>
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<td>14.96</td>
<td>6.00</td>
<td>Astrix YN</td>
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<tr>
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<td>1</td>
<td>..</td>
<td>14.05</td>
<td>6.00</td>
<td>Cartia AS</td>
</tr>
<tr>
<td>4076M</td>
<td>aspirin 100 mg tablet, 90</td>
<td>1</td>
<td>1</td>
<td>..</td>
<td>16.01</td>
<td>6.00</td>
<td>Cardiprin 100 RC</td>
</tr>
</tbody>
</table>

**CLOPIDOGREL**

Authority required

For use in patients pre- and post-angioplasty

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>Dispensed Price for Max. Qty $</th>
<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>4179Y</td>
<td>clopidogrel 75 mg tablet, 28</td>
<td>1</td>
<td>3</td>
<td>..</td>
<td>21.01</td>
<td>6.00</td>
<td>a APO-Clopidogrel TX</td>
</tr>
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<td>a Chem mart Clopidogrel CH</td>
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<td>a Iscover AV</td>
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<td>a Plax AF</td>
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<td></td>
<td></td>
<td>a Plavix SW</td>
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<td>a Terry White Chemists Clopidogrel TW</td>
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### BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS

### IRRIGATING SOLUTIONS

**Salt solutions**

<table>
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<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>Dispensed Price for Max. Qty $</th>
<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>4460R</td>
<td>sodium chloride 0.9% (4.5 g/500 mL) solution, 1 x 500 mL bottle</td>
<td>‡1</td>
<td>2</td>
<td>..</td>
<td>10.67</td>
<td>6.00</td>
<td>Baxter Healthcare Pty Ltd BX</td>
</tr>
<tr>
<td>4461T</td>
<td>sodium chloride 0.9% (9 g/1000 mL) solution, 1 x 1000 mL bottle</td>
<td>‡1</td>
<td>2</td>
<td>..</td>
<td>10.99</td>
<td>6.00</td>
<td>Baxter Healthcare Pty Ltd BX</td>
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**Note**

The enteric coated preparations are for patients with a significant risk of gastrointestinal bleeding.
<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
<th>Dispensed Price for Max. Qty $</th>
<th>Premium $</th>
<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>4039N</td>
<td>ZINC OXIDE + PERU BALSAM + BENZYL BENZOATE</td>
<td>‡1</td>
<td>1</td>
<td>..</td>
<td>14.78</td>
<td>6.00</td>
<td>Anusol JT</td>
</tr>
<tr>
<td>4040P</td>
<td>ZINC OXIDE + PERU BALSAM + BENZYL BENZOATE</td>
<td>‡1</td>
<td>1</td>
<td>..</td>
<td>13.69</td>
<td>6.00</td>
<td>Anusol JT</td>
</tr>
</tbody>
</table>
# DERMATOLOGICALS

## ANTIFUNGALS FOR DERMATOLOGICAL USE

### Antibiotics

**NYSTATIN**

- **Code**: 4001N
- **Name**: nystatin 100 000 international units/g cream, 15 g
- **Maximum Quantity (Packs)**: 1
- **No. of Rpts**: 1
- **Dispensed Price for Max. Qty $**: 12.83
- **Maximum Recordable Value for Safety Net $**: 6.00
- **Brand Name and Manufacturer**: Mycostatin FM

*Imidazole and triazole derivatives*

**CLOTRIMAZOLE**

- **Code**: 4004R
- **Name**: clotrimazole 1% (10 mg/g) cream, 20 g
- **Maximum Quantity (Packs)**: 1
- **No. of Rpts**: 1
- **Dispensed Price for Max. Qty $**: 9.18
- **Maximum Recordable Value for Safety Net $**: 6.00
- **Brand Name and Manufacturer**: Clonea AF

**KETOCONAZOLE**

- **Code**: 4007X
- **Name**: ketoconazole 2% (20 mg/g) shampoo, 100 mL
- **Maximum Quantity (Packs)**: 1
- **No. of Rpts**: ..
- **Dispensed Price for Max. Qty $**: 19.71
- **Maximum Recordable Value for Safety Net $**: 6.00
- **Brand Name and Manufacturer**: Sebizole GN

- **Code**: 4008Y
- **Name**: ketoconazole 2% (20 mg/g) shampoo, 60 mL
- **Maximum Quantity (Packs)**: 1
- **No. of Rpts**: ..
- **Dispensed Price for Max. Qty $**: 18.65
- **Maximum Recordable Value for Safety Net $**: 6.00
- **Brand Name and Manufacturer**: Nizoral 2% JT

**MICONAZOLE**

- **Code**: 4341L
- **Name**: miconazole 2% solution, 30 mL
- **Maximum Quantity (Packs)**: 1
- **No. of Rpts**: 1
- **Dispensed Price for Max. Qty $**: 19.81
- **Maximum Recordable Value for Safety Net $**: 6.00
- **Brand Name and Manufacturer**: Daktarin Tincture JT

- **Code**: 4454K
- **Name**: miconazole nitrate 2% (20 mg/g) cream, 30 g
- **Maximum Quantity (Packs)**: 1
- **No. of Rpts**: 1
- **Dispensed Price for Max. Qty $**: 15.13
- **Maximum Recordable Value for Safety Net $**: 6.00
- **Brand Name and Manufacturer**: Daktarin JT

- **Code**: 4473K
- **Name**: miconazole nitrate 2% (20 mg/g) cream, 40 g
- **Maximum Quantity (Packs)**: 1
- **No. of Rpts**: 1
- **Dispensed Price for Max. Qty $**: 14.02
- **Maximum Recordable Value for Safety Net $**: 6.00
- **Brand Name and Manufacturer**: Resolve Thrush EO

### Other antifungals for topical use

**AMOROLFINE**

- **Code**: 4010C
- **Name**: amorolfine 5% application, 5 mL
- **Maximum Quantity (Packs)**: 1
- **No. of Rpts**: 1
- **Dispensed Price for Max. Qty $**: 86.85
- **Maximum Recordable Value for Safety Net $**: 6.00
- **Brand Name and Manufacturer**: Aporyl TX

- **Name**: amorolfine 5% application, 30 mL
- **Dispensed Price for Max. Qty $**: 96.48
- **Maximum Recordable Value for Safety Net $**: 6.00
- **Brand Name and Manufacturer**: Loceryl GA

**CICLOPIROX**

- **Code**: 4106D
- **Name**: ciclopirox olamine 1.5% (15 mg/g) shampoo, 60 mL
- **Maximum Quantity (Packs)**: 1
- **No. of Rpts**: ..
- **Dispensed Price for Max. Qty $**: 19.08
- **Maximum Recordable Value for Safety Net $**: 6.00
- **Brand Name and Manufacturer**: Stieprox Liquid GK

**TERBINAFINE**

- **Code**: 4463X
- **Name**: terbinafine 1% gel, 15 g
- **Maximum Quantity (Packs)**: 1
- **No. of Rpts**: ..
- **Dispensed Price for Max. Qty $**: 23.69
- **Maximum Recordable Value for Safety Net $**: 6.00
- **Brand Name and Manufacturer**: Lamisil DermGel NC

- **Code**: 4473K
- **Name**: terbinafine hydrochloride 1% cream, 15 g
- **Maximum Quantity (Packs)**: 1
- **No. of Rpts**: ..
- **Dispensed Price for Max. Qty $**: 22.23
- **Maximum Recordable Value for Safety Net $**: 6.00
- **Brand Name and Manufacturer**: Lamisil NC

**TOLNAFTATE**

- **Code**: 4481W
- **Name**: tolnaftate 0.07% (700 microgram/g) spray, 100 g
- **Maximum Quantity (Packs)**: 1
- **No. of Rpts**: ..
- **Dispensed Price for Max. Qty $**: 15.43
- **Maximum Recordable Value for Safety Net $**: 6.00
- **Brand Name and Manufacturer**: Tinaderm MK

### ANTIFUNGALS FOR SYSTEMIC USE

**Antifungals for systemic use**

**TERBINAFINE**

- **Authority required**

---
<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Dispensed Price for Max. Qty $</th>
<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>4011D</td>
<td>terbinafine 250 mg tablet, 42</td>
<td>45.58</td>
<td>6.00</td>
<td>GenRx Terbinafine GX</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Lamisil (Novartis Pharmaceuticals Australia Pty Limited) NV</td>
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<td>Tamsil QA</td>
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<td></td>
<td></td>
<td>Terbinafine-DP GN</td>
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<td></td>
<td></td>
<td></td>
<td>Terbinafine Sandoz SZ</td>
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<td>Tinasil AF</td>
</tr>
</tbody>
</table>

**EMOLLIENTS AND PROTECTIVES**

**Silicone products**

**DIMETHICONE-350 + GLYCEROL**

*Restricted benefit*
For colostomy and ileostomy use

*Restricted benefit*
For use by paraplegic and quadriplegic patients

*Restricted benefit*
For use with surgical appliances

<table>
<thead>
<tr>
<th>Code</th>
<th>Name and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>Dispensed Price for Max. Qty $</th>
<th>Maximum Recordable Value for Safety Net $</th>
</tr>
</thead>
<tbody>
<tr>
<td>4551M</td>
<td>dimethicone-350 15% (150 mg/g) + glycerol 2% (20 mg/g) cream, 500 g</td>
<td>‡1</td>
<td>..</td>
<td>..</td>
<td>26.75</td>
<td>6.00</td>
</tr>
<tr>
<td>4556T</td>
<td>dimethicone-350 15% (150 mg/g) + glycerol 2% (20 mg/g) cream, 75 g</td>
<td>‡1</td>
<td>..</td>
<td>..</td>
<td>12.87</td>
<td>6.00</td>
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</tbody>
</table>

**Soft paraffin and fat products**

**WOOL ALCOHOLS**

wool alcohols 6% (60 mg/g) ointment, 100 g

<table>
<thead>
<tr>
<th>Code</th>
<th>Name and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>Dispensed Price for Max. Qty $</th>
<th>Maximum Recordable Value for Safety Net $</th>
</tr>
</thead>
<tbody>
<tr>
<td>4041Q</td>
<td>wool alcohols 6% (60 mg/g) ointment, 100 g</td>
<td>‡1</td>
<td>1</td>
<td>..</td>
<td>14.52</td>
<td>6.00</td>
</tr>
</tbody>
</table>

**Carbamide products**

**UREA**

urea 10% (100 mg/g) cream, 100 g

<table>
<thead>
<tr>
<th>Code</th>
<th>Name and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
<th>Premium $</th>
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<th>Maximum Recordable Value for Safety Net $</th>
</tr>
</thead>
<tbody>
<tr>
<td>4042R</td>
<td>urea 10% (100 mg/g) cream, 100 g</td>
<td>‡1</td>
<td>2</td>
<td>..</td>
<td>12.53</td>
<td>6.00</td>
</tr>
<tr>
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</tbody>
</table>

**Other emollients and protectives**

**CARMELLOSE SODIUM + GELATIN + PECTIN**
carmellose sodium 16.7% + gelatin 16.7% + pectin 16.7% paste: oromucosal, 5 g

<table>
<thead>
<tr>
<th>Code</th>
<th>Name and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>Dispensed Price for Max. Qty $</th>
<th>Maximum Recordable Value for Safety Net $</th>
</tr>
</thead>
<tbody>
<tr>
<td>4518T</td>
<td>carmellose sodium 16.7% + gelatin 16.7% + pectin 16.7% paste: oromucosal, 5 g</td>
<td>‡1</td>
<td>..</td>
<td>..</td>
<td>12.19</td>
<td>6.00</td>
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**SKIN EMOLLIENT**

Bath oil 500 mL, 1

<table>
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<th>Code</th>
<th>Name and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>Dispensed Price for Max. Qty $</th>
<th>Maximum Recordable Value for Safety Net $</th>
</tr>
</thead>
<tbody>
<tr>
<td>4122Y</td>
<td>SKIN EMOLLIENT Bath oil 500 mL, 1</td>
<td>‡1</td>
<td>2</td>
<td>..</td>
<td>17.69</td>
<td>6.00</td>
</tr>
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</tr>
</tbody>
</table>

**SKIN EMOLLIENT Lotion 500 mL, 1**

<table>
<thead>
<tr>
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<th>Name and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
<th>Premium $</th>
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<th>Maximum Recordable Value for Safety Net $</th>
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</thead>
<tbody>
<tr>
<td>4107E</td>
<td>SKIN EMOLLIENT Lotion 500 mL, 1</td>
<td>‡1</td>
<td>2</td>
<td>..</td>
<td>17.69</td>
<td>6.00</td>
</tr>
</tbody>
</table>

**PROTECTIVES AGAINST UV-RADIATION**

**Protectives against UV-radiation for topical use**

**SUNSCREENS**

Cream 75 g, 1

<table>
<thead>
<tr>
<th>Code</th>
<th>Name and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>Dispensed Price for Max. Qty $</th>
<th>Maximum Recordable Value for Safety Net $</th>
</tr>
</thead>
<tbody>
<tr>
<td>4307Q</td>
<td>SUNSCREENS Cream 75 g, 1</td>
<td>‡1</td>
<td>2</td>
<td>..</td>
<td>17.37</td>
<td>6.00</td>
</tr>
</tbody>
</table>

Lotion (non-alcoholic) 125 mL, 1

<table>
<thead>
<tr>
<th>Code</th>
<th>Name and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
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<th>Maximum Recordable Value for Safety Net $</th>
</tr>
</thead>
<tbody>
<tr>
<td>4546G</td>
<td>SUNSCREENS Lotion (non-alcoholic) 125 mL, 1</td>
<td>‡1</td>
<td>2</td>
<td>..</td>
<td>16.32</td>
<td>6.00</td>
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<td>Code</td>
<td>Name, Restriction, Manner of Administration</td>
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<td>No. of Rpts</td>
<td>Premium $</td>
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<td>Maximum Recordable Value for Safety Net $</td>
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<td>------------------------------</td>
<td>---------------------------------------------</td>
</tr>
<tr>
<td>4308R</td>
<td>lignocaine hydrochloride anhydrous 2% (20 mg/mL) oral liquid, 200 mL</td>
<td>1</td>
<td>..</td>
<td>..</td>
<td>95.37</td>
<td>6.00</td>
</tr>
<tr>
<td>4408B</td>
<td>PINE TAR WITH TRIETHANOLAMINE LAURYL SULFATE</td>
<td>1</td>
<td>2</td>
<td>..</td>
<td>23.26</td>
<td>6.00</td>
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<tr>
<td>4348W</td>
<td>mupirocin 2% (20 mg/g) cream, 15 g</td>
<td>1</td>
<td>..</td>
<td>..</td>
<td>17.59</td>
<td>6.00</td>
</tr>
<tr>
<td>4350Y</td>
<td>mupirocin 2% (20 mg/g) ointment, 15 g</td>
<td>1</td>
<td>..</td>
<td>..</td>
<td>17.59</td>
<td>6.00</td>
</tr>
<tr>
<td>4390C</td>
<td>podophyllotoxin 0.15% (1.5 mg/g) cream, 5 g</td>
<td>1</td>
<td>..</td>
<td>..</td>
<td>53.00</td>
<td>6.00</td>
</tr>
<tr>
<td>4566H</td>
<td>podophyllotoxin 0.5% solution, 3.5 mL</td>
<td>1</td>
<td>..</td>
<td>..</td>
<td>40.09</td>
<td>6.00</td>
</tr>
<tr>
<td>2464Q</td>
<td>ingenol mebutate 0.015% gel, 3 x 470 mg tubes</td>
<td>1</td>
<td>..</td>
<td>..</td>
<td>139.60</td>
<td>6.00</td>
</tr>
</tbody>
</table>

**ANTIPRURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC.**

**ANIPRURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC.**

**Anesthetics for topical use**

**LIGNOCAIN**

- **Code:** 4308R
- **Name:** lignocaine hydrochloride anhydrous 2% (20 mg/mL) oral liquid, 200 mL
- **Max. Qty (Packs):** 1
- **No. of Rpts:** ..
- **Premium $:** ..
- **Dispensed Price for Max. Qty $:** 95.37
- **Maximum Recordable Value for Safety Net $:** 6.00
- **Brand Name and Manufacturer:** Xylocaine Viscous AP

**Other antipruritics**

- **PINE TAR WITH TRIETHANOLAMINE LAURYL SULFATE**
  - **Note:** For patients who have failed to respond to simple moisturising agents.

- **Code:** 4408B
- **Name:** PINE TAR WITH TRIETHANOLAMINE LAURYL SULFATE Solution 23 mg-60 mg per mL (2.3%-6%), 500 mL
- **Max. Qty (Packs):** 1
- **No. of Rpts:** 2
- **Premium $:** ..
- **Dispensed Price for Max. Qty $:** 23.26
- **Maximum Recordable Value for Safety Net $:** 6.00
- **Brand Name and Manufacturer:** Pinetarsol EO

**ANTIPSORIATICS**

**ANTIPSORIATICS FOR TOPICAL USE**

**Tars**

- **Code:** 4505D
- **Name:** coal tar solution 5% + phenol 0.5% + sulfur-precipitated 0.5% gel, 30 g
- **Max. Qty (Packs):** 1
- **No. of Rpts:** 2
- **Premium $:** ..
- **Dispensed Price for Max. Qty $:** 16.36
- **Maximum Recordable Value for Safety Net $:** 6.00
- **Brand Name and Manufacturer:** Egopsoryl-TA EO

**ANTIBIOTICS AND CHEMOTHERAPEUTICS FOR DERMATOLOGICAL USE**

**ANTIBIOTICS FOR TOPICAL USE**

**Other antibiotics for topical use**

- **MUPIROCIN**
  - **Restricted benefit**
  - **Name:** mupirocin 2% (20 mg/g) cream, 15 g
  - **Max. Qty (Packs):** 1
  - **No. of Rpts:** ..
  - **Premium $:** ..
  - **Dispensed Price for Max. Qty $:** 17.59
  - **Maximum Recordable Value for Safety Net $:** 6.00
  - **Brand Name and Manufacturer:** Bactroban GK

- **MUPIROCIN**
  - **Restricted benefit**
  - **Name:** mupirocin 2% (20 mg/g) ointment, 15 g
  - **Max. Qty (Packs):** 1
  - **No. of Rpts:** ..
  - **Premium $:** ..
  - **Dispensed Price for Max. Qty $:** 17.59
  - **Maximum Recordable Value for Safety Net $:** 6.00
  - **Brand Name and Manufacturer:** Bactroban GK

**CHEMOTHERAPEUTICS FOR TOPICAL USE**

**Antivirals**

- **PODOPHYLLOTOXIN**
  - **Authority required**
  - **Name:** podophyllotoxin 0.15% (1.5 mg/g) cream, 5 g
  - **Max. Qty (Packs):** 1
  - **No. of Rpts:** ..
  - **Premium $:** ..
  - **Dispensed Price for Max. Qty $:** 53.00
  - **Maximum Recordable Value for Safety Net $:** 6.00
  - **Brand Name and Manufacturer:** Wartec Cream GK

- **PODOPHYLLOTOXIN**
  - **Authority required**
  - **Name:** podophyllotoxin 0.5% solution, 3.5 mL
  - **Max. Qty (Packs):** 1
  - **No. of Rpts:** ..
  - **Premium $:** ..
  - **Dispensed Price for Max. Qty $:** 40.09
  - **Maximum Recordable Value for Safety Net $:** 6.00
  - **Brand Name and Manufacturer:** Condyline Paint NQ

**Other chemotherapeutics**

- **INGERON MEButATE**
  - **Authority required**
  - **Name:** ingenol mebutate 0.015% gel, 3 x 470 mg tubes
  - **Max. Qty (Packs):** 1
  - **No. of Rpts:** ..
  - **Premium $:** ..
  - **Dispensed Price for Max. Qty $:** 139.60
  - **Maximum Recordable Value for Safety Net $:** 6.00
  - **Brand Name and Manufacturer:** Picato LO
<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>Dispensed Price for Max. Qty $</th>
<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>2468X</td>
<td>ingelon mebutate 0.05% gel, 2 x 470 mg tubes</td>
<td>1</td>
<td>..</td>
<td>..</td>
<td>139.60</td>
<td>6.00</td>
<td>Picato LO</td>
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**CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS**

**CORTICOSTEROIDS, PLAIN**

*Corticosteroids, potent (group III)*

**BETAMETHASONE VALERATE**

4131K betamethasone (as valerate) 0.1% (1 mg/g) cream, 30 g ¶1 2 .. .. 22.77 6.00 Betnovate QA

4132L betamethasone (as valerate) 0.1% (1 mg/g) ointment, 30 g ¶1 2 .. .. 22.77 6.00 Betnovate QA

**MOMETASONE**

*Note*

Application to large areas of skin for longer than four weeks is not recommended.

4342M mometasone furoate 0.1% (1 mg/g) cream, 50 g ¶1 .. .. .. 33.82 6.00 Elocon MK

4343N mometasone furoate 0.1% (1 mg/g) ointment, 50 g ¶1 .. .. .. 33.82 6.00 Elocon MK

**ANTISEPTICS AND DISINFECTANTS**

**ANTISEPTICS AND DISINFECTANTS**

*Iodine products*

4411E povidone-iodine 10% solution, 100 mL ¶1 .. .. .. 22.45 6.00 Betadine Antiseptic Liquid SW

**OTHER DERMATOLOGICAL PREPARATIONS**

**OTHER DERMATOLOGICAL PREPARATIONS**

*Medicated shampoos*

4447C coal tar solution 1% (10 mg/g) + tar 1% (10 mg/g) + salicylic acid 2% (20 mg/g) solution, 250 mL ¶1 2 .. .. 19.18 6.00 Sebitar EO

**SALICYLIC ACID + BENZALKONIUM CHLORIDE + ALCOHOL + COAL TAR SOLUTION + POLYOXYETHYLENE ETHERS**

4560B SALICYLIC ACID with COAL TAR SOLUTION scalp cleanser 20 mg-50 mg per mL (2%-5%), 200 mL, 1 ¶1 2 .. .. 20.72 6.00 Ionil-T GA

**SELENIUM SULFIDE**

4452H selenium sulfide 2.5% (25 mg/mL) shampoo, 125 mL ¶1 .. .. .. 14.48 6.00 Selsun DQ

**TAR + CADE OIL + COAL TAR + ARACHIS OIL EXTRACT OF COAL TAR**

4405W tar 0.3% (300 microgram/mL) + cade oil 0.03% (300 microgram/mL) + coal tar 0.01% (100 microgram/mL) + arachis oil extract of coal tar 0.3% (3 mg/mL) lotion, 300 mL ¶1 2 .. .. 24.48 6.00 Polytar GK

**Wart and anti-corn preparations**

**LACTIC ACID + SALICYLIC ACID**

4386W lactic acid 16.7% (167 mg/mL) + salicylic acid 16.7% (167 mg/mL) application, 15 mL ¶1 .. .. .. 18.49 6.00 Duofilm Solution GK
**DERMATOLOGICALS**

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
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<th>Dispensed Price for Max. Qty $</th>
<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
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<tr>
<td><strong>Other dermatologica</strong>ls<strong>s</strong></td>
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<tr>
<td><strong>DICLOFENAC</strong></td>
<td>Authority required</td>
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<tr>
<td></td>
<td>For the management of actinic keratoses in patients where other standard treatments are inappropriate, and topical drug therapy is required as field treatment for clinically visible and subclinical lesions</td>
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<tr>
<td></td>
<td><strong>Note</strong></td>
<td>Maximum quantity of four tubes (original + 3 repeats) in 12 months.</td>
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<tr>
<td>4046Y</td>
<td>diclofenac sodium 3% gel, 25 g‡</td>
<td>1</td>
<td>3</td>
<td>‚</td>
<td>58.53</td>
<td>6.00</td>
<td>Solaraze 3% Gel CS</td>
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<tr>
<td><strong>ICHTHAMMOL</strong></td>
<td></td>
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<tr>
<td></td>
<td><strong>Note</strong></td>
<td>For patients who have failed to respond to simple moisturising agents.</td>
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</tr>
<tr>
<td>4281H</td>
<td>ichthammol Cream 5 mg-10 mg-10 mg per g (0.5%-1%-1%), 50 g, 1‡</td>
<td>1</td>
<td>2</td>
<td>‚</td>
<td>18.44</td>
<td>6.00</td>
<td>Egoderm Cream EO</td>
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<tr>
<td><strong>ICHTHAMMOL + ZINC OXIDE</strong></td>
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<td></td>
<td><strong>Note</strong></td>
<td>For patients who have failed to respond to simple moisturising agents.</td>
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</tr>
<tr>
<td>4280G</td>
<td>ichthammol 1% (10 mg/g) + zinc oxide 15% (150 mg/g) ointment, 50 g‡</td>
<td>1</td>
<td>2</td>
<td>‚</td>
<td>18.44</td>
<td>6.00</td>
<td>Egoderm Ointment EO</td>
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<td><strong>IMIQUIMOD</strong></td>
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<td></td>
<td>Solar keratosis</td>
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<tr>
<td></td>
<td><strong>Clinical criteria:</strong></td>
<td>Patient must require topical drug therapy on the face and scalp as field treatment for clinically visible and subclinical lesions where other standard treatments are inappropriate.</td>
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<tr>
<td></td>
<td><strong>Note</strong></td>
<td>Pharmaceutical benefits that have the form imiquimod single use sachets and pharmaceutical benefits that have the form imiquimod multi-use pump are equivalent for the purposes of substitution.</td>
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<td>4134N</td>
<td>imiquimod 5% cream, 12 x 250 mg sachets</td>
<td>1</td>
<td>1</td>
<td>‚</td>
<td>135.72</td>
<td>6.00</td>
<td>a Aldara IA</td>
</tr>
<tr>
<td></td>
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<td></td>
<td></td>
<td></td>
<td>a Aldiq QA</td>
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<td></td>
<td></td>
<td>a APO-imiquimod TX</td>
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<tr>
<td>10106X</td>
<td>imiquimod 5% cream, 2 x 2 g pump packs</td>
<td>1</td>
<td>1</td>
<td>‚</td>
<td>135.72</td>
<td>6.00</td>
<td>a Aldara Pump IA</td>
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<td>a Aldiq QA</td>
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<td><strong>IMIQUIMOD</strong></td>
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<tr>
<td></td>
<td>Primary treatment of histopathologically confirmed superficial basal cell carcinoma where other standard treatments are inappropriate and topical drug therapy is required</td>
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<td>4559Y</td>
<td>imiquimod 5% cream, 12 x 250 mg sachets</td>
<td>1</td>
<td>1</td>
<td>‚</td>
<td>135.72</td>
<td>6.00</td>
<td>a Aldara IA</td>
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<td>a Aldiq QA</td>
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<td>a APO-imiquimod TX</td>
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<td><strong>PANTHENOL</strong></td>
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<tr>
<td></td>
<td><strong>Note</strong></td>
<td>To be used in conjunction with the scalp cleanser salicylic acid with coal tar solution and pine tar (code 4447C).</td>
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<tr>
<td>4510J</td>
<td>panthenol conditioner, 200 g‡</td>
<td>1</td>
<td>2</td>
<td>‚</td>
<td>14.59</td>
<td>6.00</td>
<td>SebiRinse EO</td>
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<tr>
<td><strong>PARAFFIN LIGHT LIQUID + COCOAMPHODIACETATE DISODIUM</strong></td>
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<tr>
<td>4549K</td>
<td>paraffin light liquid 3.5% (35 mg/mL) + cocoamphodiacetate disodium 3% (30 mg/mL) lotion, 500 mL‡</td>
<td>1</td>
<td>2</td>
<td>‚</td>
<td>21.08</td>
<td>6.00</td>
<td>Hamilton Skin Therapy Wash KY</td>
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<tr>
<td><strong>ZINC OXIDE + MAIZE STARCH + CHLORPHENESIN + TALC-PURIFIED</strong></td>
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</tr>
<tr>
<td>4497Q</td>
<td>zinc oxide 25% (250 mg/g) + maize starch 55.85% (558.5 mg/g) + chlorphenesin 1% (10 mg/g) + talc-</td>
<td>1</td>
<td>1</td>
<td>‚</td>
<td>12.59</td>
<td>6.00</td>
<td>Z.S.C. QA</td>
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<tr>
<td>Code</td>
<td>Name, Restriction, Manner of Administration and Form</td>
<td>Max. Qty (Packs)</td>
<td>No. of Rpts</td>
<td>Premium $</td>
<td>Dispensed Price for Max. Qty $</td>
<td>Maximum Recordable Value for Safety Net $</td>
<td>Brand Name and Manufacturer</td>
</tr>
<tr>
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</tr>
<tr>
<td></td>
<td>purified 18.07% (180.7 mg/g) powder: dusting, 100 g</td>
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</table>
## GENITO URINARY SYSTEM AND SEX HORMONES

### GYNECOLOGICAL ANTIINFECTIVES AND ANTISEPTICS

#### ANTIINFECTIVES AND ANTISEPTICS, EXCL. COMBINATIONS WITH CORTICOSTEROIDS

<table>
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<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration</th>
<th>Max. Qty (Packs)</th>
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<th>Premium $</th>
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<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
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<tr>
<td>4013F</td>
<td>NYSTATIN</td>
<td>‡1 1</td>
<td>..</td>
<td>14.13</td>
<td>6.00</td>
<td>Nilstat</td>
<td>QA</td>
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<tr>
<td></td>
<td>nystatin 20 000 international units/g vaginal cream, 75 g</td>
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<tr>
<td>4016J</td>
<td>CLOTRIMAZOLE</td>
<td>‡1 1</td>
<td>..</td>
<td>15.42</td>
<td>6.00</td>
<td>APO-Clotrimazole 6 Day Cream</td>
<td>TX</td>
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<tr>
<td></td>
<td>clotrimazole 1% (10 mg/g) cream, 35 g</td>
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</tr>
<tr>
<td>4017K</td>
<td>CLOTRIMAZOLE</td>
<td>‡1 1</td>
<td>..</td>
<td>15.42</td>
<td>6.00</td>
<td>APO-Clotrimazole 3 Day Cream</td>
<td>TX</td>
</tr>
<tr>
<td></td>
<td>clotrimazole 2% (20 mg/g) cream, 20 g</td>
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#### OTHER GYNECOLOGICALS

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<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>4434J</td>
<td>ACETIC ACID + HYDROXYQUINOLINE + RICINOLEIC ACID</td>
<td>‡1 1</td>
<td>..</td>
<td>33.24</td>
<td>6.00</td>
<td>Aci-Jel</td>
<td>CU</td>
</tr>
<tr>
<td></td>
<td>acetic acid 0.94% + hydroxyquinoline sulfate 0.025% + ricinoleic acid 0.75% vaginal gel, 100 g</td>
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</tbody>
</table>

### UROLOGICALS

#### Drugs used in erectile dysfunction

**ALPROSTADIL**

**Authority required**
Males with vasculogenic, psychogenic or neurogenic erectile dysfunction

**Clinical criteria:**
Patient must have a specific accepted war-caused or service-related disability.

Authorisation will not be given for any additional prescriptions within 6 months or for any increased quantities or repeats.

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>Dispensed Price for Max. Qty $</th>
<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>10031Y</td>
<td>alprostadil 10 microgram injection [1 x 10 microgram vial] (&amp;) inert substance diluent [1 syringe], 1 pack</td>
<td>6 3</td>
<td>..</td>
<td>*105.82</td>
<td>6.00</td>
<td>Caverject</td>
<td>PF</td>
</tr>
<tr>
<td>10030X</td>
<td>alprostadil 20 microgram injection [1 x 20 microgram vial] (&amp;) inert substance diluent [1 syringe], 1 pack</td>
<td>6 3</td>
<td>..</td>
<td>*133.18</td>
<td>6.00</td>
<td>Caverject</td>
<td>PF</td>
</tr>
</tbody>
</table>

**SILDENAFIL**

**Authority required**
Specific accepted war-caused or service-related disabilities for males with vasculogenic, psychogenic or neurogenic erectile dysfunction.

Authorisation will not be given for any additional prescriptions within 6 months or for any increased quantities or repeats.

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration</th>
<th>Max. Qty (Packs)</th>
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<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>4586J</td>
<td>sildenafil 100 mg tablet, 4</td>
<td>1 5</td>
<td>..</td>
<td>73.33</td>
<td>6.00</td>
<td>a APO-Sildenafil</td>
<td>TX</td>
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<tr>
<td>4584G</td>
<td>sildenafil 25 mg tablet, 4</td>
<td>1 5</td>
<td>..</td>
<td>86.02</td>
<td>6.00</td>
<td>a Viag ra</td>
<td>PF</td>
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</tr>
<tr>
<td>4585H</td>
<td>sildenafil 50 mg tablet, 4</td>
<td>1 5</td>
<td>..</td>
<td>64.32</td>
<td>6.00</td>
<td>a Viag ra</td>
<td>PF</td>
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</table>

**TADALAFIL**

### UROLOGICALS

#### Drugs used in erectile dysfunction

**ALPROSTADIL**

**Authority required**
Males with vasculogenic, psychogenic or neurogenic erectile dysfunction

**Clinical criteria:**
Patient must have a specific accepted war-caused or service-related disability.

Authorisation will not be given for any additional prescriptions within 6 months or for any increased quantities or repeats.

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>Dispensed Price for Max. Qty $</th>
<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>10031Y</td>
<td>alprostadil 10 microgram injection [1 x 10 microgram vial] (&amp;) inert substance diluent [1 syringe], 1 pack</td>
<td>6 3</td>
<td>..</td>
<td>*105.82</td>
<td>6.00</td>
<td>Caverject</td>
<td>PF</td>
</tr>
<tr>
<td>10030X</td>
<td>alprostadil 20 microgram injection [1 x 20 microgram vial] (&amp;) inert substance diluent [1 syringe], 1 pack</td>
<td>6 3</td>
<td>..</td>
<td>*133.18</td>
<td>6.00</td>
<td>Caverject</td>
<td>PF</td>
</tr>
</tbody>
</table>

**SILDENAFIL**

**Authority required**
Specific accepted war-caused or service-related disabilities for males with vasculogenic, psychogenic or neurogenic erectile dysfunction.

Authorisation will not be given for any additional prescriptions within 6 months or for any increased quantities or repeats.

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
<th>Premium $</th>
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<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>4586J</td>
<td>sildenafil 100 mg tablet, 4</td>
<td>1 5</td>
<td>..</td>
<td>73.33</td>
<td>6.00</td>
<td>a APO-Sildenafil</td>
<td>TX</td>
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</tr>
<tr>
<td>4584G</td>
<td>sildenafil 25 mg tablet, 4</td>
<td>1 5</td>
<td>..</td>
<td>86.02</td>
<td>6.00</td>
<td>a Viag ra</td>
<td>PF</td>
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<tr>
<td>4585H</td>
<td>sildenafil 50 mg tablet, 4</td>
<td>1 5</td>
<td>..</td>
<td>64.32</td>
<td>6.00</td>
<td>a Viag ra</td>
<td>PF</td>
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</tbody>
</table>

**TADALAFIL**
<table>
<thead>
<tr>
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<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
<th>Dispensed Price for Max. Qty $</th>
<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>4596X</td>
<td>tadalafil 10 mg tablet, 4</td>
<td>1</td>
<td>5</td>
<td>98.96</td>
<td>6.00</td>
<td>Cialis LY</td>
</tr>
<tr>
<td>4597Y</td>
<td>tadalafil 20 mg tablet, 4</td>
<td>1</td>
<td>5</td>
<td>98.96</td>
<td>6.00</td>
<td>Cialis LY</td>
</tr>
</tbody>
</table>

**VARDENAFIL**

**Authority required**

Specific accepted war-caused or service-related disabilities for males with vasculogenic, psychogenic or neurogenic erectile dysfunction. Authorisation will not be given for any additional prescriptions within 6 months or for any increased quantities or repeats.

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
<th>Dispensed Price for Max. Qty $</th>
<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>4290T</td>
<td>vardenafil 10 mg tablet, 4</td>
<td>1</td>
<td>5</td>
<td>73.13</td>
<td>6.00</td>
<td>Levitra BN</td>
</tr>
<tr>
<td>4302K</td>
<td>vardenafil 20 mg tablet, 4</td>
<td>1</td>
<td>5</td>
<td>83.86</td>
<td>6.00</td>
<td>Levitra BN</td>
</tr>
</tbody>
</table>

**Other urologicals**

**BICARBONATE + CITRATE + TARTARIC ACID**

**Restricted benefit**

For relief of urinary symptoms when antibiotic or other therapy alone is inappropriate.

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
<th>Dispensed Price for Max. Qty $</th>
<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>4049D</td>
<td>sodium bicarbonate 1.76 g + citrate sodium 630 mg + citrate 720 mg + tartaric acid 890 mg oral liquid: powder for, 28 x 4 g sachets</td>
<td>1</td>
<td>4</td>
<td>13.89</td>
<td>6.00</td>
<td>Uracol GN</td>
</tr>
</tbody>
</table>

**DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY**

**Alpha-adrenoceptor antagonists**

**ALFUZOSIN**

**Authority required**

Treatment of benign prostatic hyperplasia where surgery is inappropriate, or where other drug treatment has failed or is contraindicated.

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
<th>Dispensed Price for Max. Qty $</th>
<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>4277D</td>
<td>alfuzosin hydrochloride 10 mg tablet: modified release, 30 tablets</td>
<td>1</td>
<td>5</td>
<td>63.70</td>
<td>6.00</td>
<td>Xatral SR SW</td>
</tr>
</tbody>
</table>

**DUTASTERIDE + TAMSULOSIN**

**Authority required**

Benign prostatic hyperplasia

**Clinical criteria:**

- Patient must be one in whom surgery is inappropriate; OR
- Patient must have failed to respond to other drug treatment or other drug treatment must be contraindicated.

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
<th>Dispensed Price for Max. Qty $</th>
<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>10102Q</td>
<td>dutasteride 500 microgram + tamsulosin hydrochloride 400 microgram capsule: modified release, 30</td>
<td>1</td>
<td>5</td>
<td>35.63</td>
<td>6.00</td>
<td>Duodart 500ug/400ug GK</td>
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**TAMSULOSIN**

**Authority required**

Treatment of benign prostatic hyperplasia where surgery is inappropriate, or where other drug treatment has failed or is contraindicated.

<table>
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<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
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<tbody>
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<td>4070F</td>
<td>tamsulosin hydrochloride 400 microgram tablet: modified release, 30</td>
<td>1</td>
<td>5</td>
<td>63.70</td>
<td>6.00</td>
<td>Flomaxtra CS</td>
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**TERAZOSIN**

**Authority required**

Treatment of benign prostatic hyperplasia where surgery is inappropriate, or where other drug treatment has failed or is contraindicated.

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
<th>Dispensed Price for Max. Qty $</th>
<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
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<tr>
<td>4396J</td>
<td>terazosin 1 mg tablet [7 tablets] (6$)</td>
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<td>20.39</td>
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<td>Hytrin AB</td>
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<td>86.40</td>
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<tr>
<td>4397K</td>
<td>terazosin 2 mg tablet, 28</td>
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<td>5</td>
<td>42.03</td>
<td>6.00</td>
<td>Hytrin AB</td>
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### GENITO URINARY SYSTEM AND SEX HORMONES

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<th>Brand Name and Manufacturer</th>
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</thead>
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<tr>
<td>4398L</td>
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<td>5</td>
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<td>58.53</td>
<td>6.00</td>
<td>Hytrin AB</td>
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<tr>
<td></td>
<td><strong>Testosterone-5-alpha reductase inhibitors</strong></td>
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<tr>
<td></td>
<td><strong>DUTASTERIDE</strong></td>
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<tr>
<td></td>
<td>Benign prostatic hyperplasia</td>
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<tr>
<td></td>
<td><strong>Clinical criteria:</strong></td>
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<tr>
<td></td>
<td>Patient must be one in whom surgery is inappropriate; OR</td>
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<tr>
<td></td>
<td>Patient must have failed to respond to other drug treatment or other drug treatment must be contraindicated.</td>
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<td><strong>FINASTERIDE</strong></td>
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<td></td>
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<td></td>
<td>Treatment of benign prostatic hyperplasia where surgery is inappropriate, or where other drug treatment has failed or is contraindicated</td>
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<td>91.60</td>
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<td>a Pharmacy Choice Finasteride</td>
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<td>a Finasteride RBX</td>
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<td>97.66</td>
<td>6.00</td>
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<tr>
<td></td>
<td>a Finasteride-GA 5</td>
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<td></td>
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<td>a Pharmacor Finasteride</td>
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<td>a Proscar</td>
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<td>----------------------------------</td>
</tr>
<tr>
<td>4115N</td>
<td><strong>AZITHROMYCIN</strong>&lt;br&gt;&lt;br&gt;<em>Restricted benefit</em>&lt;br&gt;Upper and lower respiratory tract infections</td>
<td>1 .. ..</td>
<td>31.85</td>
<td>6.00</td>
<td>a APO-Azithromycin TX</td>
<td></td>
<td>a Azithromycin-GA UA&lt;br&gt;a Azithromycin Sandoz SZ&lt;br&gt;a Chem mart CH&lt;br&gt;a Terry White Chemists TW&lt;br&gt;a Zithromax PF&lt;br&gt;a Zitrocin GN&lt;br&gt;a Zedd 500 QA</td>
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</tbody>
</table>
**ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS**

### ANTINEOPLASTIC AGENTS

#### ANTIMETABOLITES

**Pyrimidine analogues**

<table>
<thead>
<tr>
<th>Code</th>
<th>Name</th>
<th>Restriction</th>
<th>Manner of Administration</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
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<th>Premium $</th>
<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>4222F</td>
<td>FLUOROURACIL</td>
<td>riet</td>
<td>fluorouracil 5% (50 mg/g) cream, 20 g</td>
<td>1 §</td>
<td>..</td>
<td>..</td>
<td>60.96</td>
<td>6.00</td>
<td>Efudix</td>
</tr>
</tbody>
</table>

### IMMUNOSUPPRESSANTS

**Tumor necrosis factor alpha (TNF-) inhibitors**

**INFLIXIMAB**

**Authority required**

Initial treatment, in combination with methotrexate, of specific accepted war-caused or service-related disability of refractory rheumatoid arthritis. Initial treatment may be prescribed by rheumatologists or consultant physicians for the reduction of signs and symptoms and prevention of structural joint damage in adult patients with active rheumatoid arthritis who satisfy all of the following criteria:

1. (a) Proven raised erythrocyte sedimentation rate (ESR) and/or C-reactive protein (CRP); and
2. (b) Proven erosive rheumatoid arthritis without end-stage disease;
3. Failure of an adequate trial of methotrexate and 2 other disease modifying anti-rheumatic drugs (such as sulfasalazine, hydroxychloroquine, leflunomide or cyclosporin) — unless these drugs were contraindicated or intolerance had developed;
4. No history of active tuberculosis requiring treatment in the last 3 years;
5. No history of opportunistic infection in the last 2 months;
6. Female patients of child-bearing age are not pregnant, not breast-feeding, and are using an effective form of contraception.

Applications for authorisation must be in writing and must include:

1. a completed authority prescription form; and
2. a completed Infliximab (Remicade) RPBS Authority Application - Supporting Information form (contact the VAPAC on 1800 552 580 for a copy of the form)

**Authority required**

Continuing treatment, in combination with methotrexate, of specific accepted war-caused or service-related disability of refractory rheumatoid arthritis. Continuing treatment may be prescribed by rheumatologists or consultant physicians, following initial therapy of 3 doses, in patients who satisfy the following criteria:

1. There is improvement in ESR and/or CRP; and
2. An ACR20 (American College of Rheumatology) response is achieved by 14 weeks after the commencement of therapy.

Applications for authorisation must be in writing and must include:

1. a completed authority prescription form; and
2. a completed Infliximab (Remicade) RPBS Authority Application - Supporting Information form (contact the VAPAC on 1800 552 580 for a copy of the form)

**Note**

Any queries concerning the arrangements to prescribe infliximab may be directed to the Veterans’ Affairs Pharmaceutical Advisory Centre (VAPAC) on 1800 552 580.

Written applications for authority to prescribe infliximab should be forwarded to:

- Reply Paid 9998
- Veterans’ Affairs Pharmaceutical Advisory Centre (VAPAC)
- Department of Veterans’ Affairs
- GPO Box 9998
- BRISBANE QLD 4001

<table>
<thead>
<tr>
<th>Code</th>
<th>Name</th>
<th>Restriction</th>
<th>Manner of Administration</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
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<th>Premium $</th>
<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>4284L</td>
<td>infliximab 100 mg injection, 1 x 100 mg vial</td>
<td></td>
<td></td>
<td>1</td>
<td>2</td>
<td>..</td>
<td>847.32</td>
<td>6.00</td>
<td>Remicade</td>
</tr>
</tbody>
</table>
## MUSCULO-SKELETAL SYSTEM

### ANTIINFAMMATORY AND ANTIRHEUMATIC PRODUCTS

#### ANTIINFAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS

**Acetic acid derivatives and related substances**

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration</th>
<th>Max. Qty (Packets)</th>
<th>No. of Rpts</th>
<th>Dispensed Price for Max. Qty</th>
<th>Premium $</th>
<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>4190M</td>
<td>diclofenac sodium 50 mg + misoprostol 200 microgram tablet, 60</td>
<td>1 2 ..</td>
<td>38.12</td>
<td>6.00</td>
<td>Arthrotec 50 PF</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Patients requiring an NSAID in whom a risk of upper gastrointestinal complications is high or with a history of peptic ulcer disease**

### TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN

#### TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN

**Preparations with salicylic acid derivatives**

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration</th>
<th>Max. Qty (Packets)</th>
<th>No. of Rpts</th>
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<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>4026X</td>
<td>methyl salicylate 25% (0.25 mL/mL) liniment, 100 mL</td>
<td>¥1 1 ..</td>
<td>10.28</td>
<td>6.00</td>
<td>Gold Cross BI</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4023R</td>
<td>methyl salicylate 50% (500 mg/g) ointment, 100 g</td>
<td>¥1 1 ..</td>
<td>12.51</td>
<td>6.00</td>
<td>Gold Cross BI</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4022Q</td>
<td>methyl salicylate 25% (250 mg/g) + menthol 4% (40 mg/g) + eucalyptus oil 10% (100 mg/g) cream, 100 g</td>
<td>¥1 1 ..</td>
<td>14.36</td>
<td>6.00</td>
<td>Gold Cross BI</td>
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### DRUGS FOR TREATMENT OF BONE DISEASES

#### DRUGS AFFECTING BONE STRUCTURE AND MINERALIZATION

**Bisphosphonates**

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration</th>
<th>Max. Qty (Packets)</th>
<th>No. of Rpts</th>
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<th>Brand Name and Manufacturer</th>
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<tr>
<td>2191H</td>
<td>risedronate sodium 35 mg (enteric coated), 4</td>
<td>1 5 ..</td>
<td>45.73</td>
<td>6.00</td>
<td>Acrit Once-a-Week AF</td>
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<td></td>
</tr>
<tr>
<td>4444X</td>
<td>risedronate sodium 35 mg tablet, 4</td>
<td>1 5 ..</td>
<td>45.73</td>
<td>6.00</td>
<td>a APO-Risedronate TX</td>
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<td>a Risedronate-GA GN</td>
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<td></td>
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<tr>
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<td>1 5 ..</td>
<td>45.73</td>
<td>6.00</td>
<td>Actonel SW</td>
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**Bisphosphonates, combinations**

<table>
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<th>Max. Qty (Packets)</th>
<th>No. of Rpts</th>
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<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>2224C</td>
<td>alendronate 70 mg + colecaciferol 140 microgram tablet, 4</td>
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<td>48.00</td>
<td>6.00</td>
<td>Fosamax Plus 70 mg/140 mcg MK</td>
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<td></td>
</tr>
<tr>
<td>2194L</td>
<td>alendronate 70 mg + colecaciferol 70 microgram tablet, 4</td>
<td>1 5 ..</td>
<td>45.51</td>
<td>6.00</td>
<td>Fosamax Plus MK</td>
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<td></td>
</tr>
</tbody>
</table>

**ALENDRONATE + COLECALCIFEROL (&) CALCIUM CARBONATE**

**Authority required**
### Risedronate (Brand) Calcium Carbonate

#### Authority required

For preservation of bone mineral density in patients on long-term glucocorticoid therapy where patients are undergoing continuous treatment with a dose equal to or greater than 7.5 mg of prednisone or equivalent per day. Prescribers need to demonstrate that the patient has been on continuous therapy for 3 months or more and demonstrate that the patient is osteopenic (bone mineral density t-score of less than -1.0)

<table>
<thead>
<tr>
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<th>No. of Rpts</th>
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<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>2273P</td>
<td>Alendronate 70 mg + colecalciferol 140 microgram tablet [4] (&amp;) calcium (as carbonate) 500 mg tablet [48], 1 pack</td>
<td>¥1 5 ..</td>
<td>45.51</td>
<td>6.00</td>
<td>Fosamax Plus D-Cal MK</td>
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<tr>
<td>2220W</td>
<td>Risedronate sodium and calcium carbonate Pack containing 4 enteric coated tablets risedronate sodium 35 mg and 24 tablets calcium carbonate 1.25 g (equivalent to 500 mg calcium), 1</td>
<td>¥1 5 ..</td>
<td>45.73</td>
<td>6.00</td>
<td>Actonel EC Combi SW</td>
<td></td>
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<tr>
<td>4059P</td>
<td>Risedronate sodium 35 mg tablet [4] (&amp;) calcium (as carbonate) 500 mg tablet [24], 28</td>
<td>¥1 5 ..</td>
<td>45.73</td>
<td>6.00</td>
<td>Acris Combi AF</td>
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<tr>
<td>2254P</td>
<td>Risedronate sodium and calcium carbonate with colecalciferol Pack containing 4 enteric coated tablets risedronate sodium 35 mg and 24 sachets containing granules of calcium carbonate 2.5 g (equivalent to 1 g calcium) with colecalciferol 22 micrograms, 1</td>
<td>¥1 5 ..</td>
<td>45.73</td>
<td>6.00</td>
<td>Actonel EC Combi D SW</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
## NERVOUS SYSTEM

### ANALGESICS

#### OPIOIDS

**Natural opium alkaloids**

**MORPHINE**

*Restricted benefit*

Chronic severe disabling pain not responding to non-narcotic analgesics

**Caution**

The risk of drug dependence is high.

**Note**

Authorities for increased maximum quantities and/or repeats will be granted only for

(i) chronic severe disabling pain associated with proven malignant neoplasia; or

(ii) chronic severe disabling pain where treatment has been initiated by a specialist with appropriate expertise in pain management.

### OTHER ANALGESICS AND ANTIPYRETICS

#### Salicylic acid and derivatives

**ASPIRIN + CODEINE**

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<th>Brand Name and Manufacturer</th>
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<td>4286N</td>
<td>aspirin 300 mg + codeine phosphate 8 mg tablet: dispersible, 40</td>
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<td>..</td>
<td>14.52</td>
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#### Anilides

**PARACETAMOL + CODEINE**

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<td>6.00</td>
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<tr>
<td>4171M</td>
<td>paracetamol 500 mg + codeine phosphate 8 mg tablet, 50</td>
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<td>13.20</td>
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<td>Codalgin FM</td>
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</table>

#### Other analgesics and antipyretics

**GABAPENTIN**

*Authority required*

To be approved for the treatment of refractory neuropathic pain not controlled by other drugs

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<td>*29.82</td>
<td>6.00</td>
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<td>..</td>
<td>*36.44</td>
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<td>..</td>
<td>55.18</td>
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<td>Buspar QA</td>
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<td>6.00</td>
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</tbody>
</table>

**ANXIOLYRICS**

* Benzodiazepine derivatives
  
  **BROMAZEPAM**
  
  Authority required
  Patients with terminal disease
  
  Authority required
  Patients with refractory phobic or anxiety states
  
  **Note**
  For short-term use and palliative care. This drug should not be used as the first line of treatment. Other PBS-listed benzodiazepines should have been adequately tried and found to be ineffective or inappropriate. Authorities for increased quantities and/or repeats may be granted to patients with terminal disease, and other patients who have been shown to be dependent on this item by an unsuccessful attempt at gradual withdrawal.

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<td>bromazepam 3 mg tablet, 30</td>
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<td>..</td>
<td>..</td>
<td>*29.82</td>
<td>6.00</td>
<td>Lexotan RO</td>
</tr>
<tr>
<td>4151L</td>
<td>bromazepam 6 mg tablet, 30</td>
<td>2</td>
<td>..</td>
<td>..</td>
<td>*36.44</td>
<td>6.00</td>
<td>Lexotan RO</td>
</tr>
</tbody>
</table>

**Azaspirodecanedione derivatives**

**BUSPIRONE**

Authority required
For the short-term treatment of anxiety

<table>
<thead>
<tr>
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<td>..</td>
<td>..</td>
<td>55.18</td>
<td>6.00</td>
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<td>..</td>
<td>38.33</td>
<td>6.00</td>
<td>Buspar QA</td>
</tr>
</tbody>
</table>

**HYPNOTICS AND SEDATIVES**

* Benzodiazepine derivatives

**FLUNITRAZEPAM**

Authority required
Patients with terminal disease

Authority required
Patients with refractory phobic or anxiety states

**Note**
For short-term use and palliative care. This drug should not be used as the first line of treatment. Other PBS-listed benzodiazepines should have been adequately tried and found to be ineffective or inappropriate. Authorities for increased quantities and/or repeats may be granted to patients with terminal disease, and other patients who have been shown to be dependent on this item by an unsuccessful attempt at gradual withdrawal.

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<td>..</td>
<td>..</td>
<td>15.22</td>
<td>6.00</td>
<td>Hypnodorm AF</td>
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</table>

**Benzodiazepine related drugs**

**ZOPICLONE**

Restricted benefit
For the short-term treatment of insomnia
### NERVOUS SYSTEM

<table>
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<tr>
<th>Code</th>
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<td>4522B</td>
<td>zopiclone 7.5 mg tablet, 30</td>
<td>22.10</td>
<td>1</td>
<td>..</td>
<td>6.00</td>
<td>a</td>
<td>25.25</td>
<td>6.00</td>
<td>a</td>
<td>Imrest AF</td>
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### OTHER NERVOUS SYSTEM DRUGS

#### DRUGS USED IN ADDICTIVE DISORDERS

**Drugs used in nicotine dependence**

**NICOTINE**

**Authority required**

Patients who have indicated that they are ready to cease smoking and who have entered a support and counselling program

**Note**

Studies have shown that successful therapy with this drug is enhanced by patient participation in a support and counselling program.

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<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>4577X</td>
<td>nicotine 10 mg/16 hours patch, 7</td>
<td>*55.12</td>
<td>2</td>
<td>..</td>
<td>6.00</td>
<td>Nicorette Patch</td>
<td>JT</td>
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<tr>
<td>4572P</td>
<td>nicotine 14 mg/24 hours patch, 7</td>
<td>*54.90</td>
<td>2</td>
<td>..</td>
<td>6.00</td>
<td>QuitX</td>
<td>AF</td>
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<td>4578Y</td>
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<td>*69.08</td>
<td>2</td>
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<td>6.00</td>
<td>Nicorette Patch</td>
<td>JT</td>
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<td>nicotine 21 mg/24 hours patch, 7</td>
<td>*58.02</td>
<td>2</td>
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<td>QuitX</td>
<td>AF</td>
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### ANTIPARASITIC PRODUCTS, INSECTICIDES AND REPELLENTS

#### ANTHELMINTICS

**ANTINEMATODAL AGENTS**

*Benzimidazole derivatives*

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<tr>
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<td>Vermox IA</td>
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## RESPIRATORY SYSTEM

### NASAL PREPARATIONS

#### DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE

**Sympathomimetics, plain**

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<th>Code</th>
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<tr>
<td>4378K</td>
<td>oxymetazoline hydrochloride 0.05% (500 microgram/mL) nasal spray, 15 mL</td>
<td>‡1 .. ..</td>
<td>17.49</td>
<td>6.00</td>
<td>Drixine</td>
<td>MK</td>
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<tr>
<td>4379L</td>
<td>oxymetazoline hydrochloride 0.05% (500 microgram/mL) nasal spray, 18 mL</td>
<td>‡1 .. ..</td>
<td>17.10</td>
<td>6.00</td>
<td>Logincin Rapid Relief</td>
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**Antiallergic agents, excl. corticosteroids**

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<td>cromoglycate sodium 2% (20 mg/mL) nasal spray, 26 mL</td>
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<td>23.25</td>
<td>6.00</td>
<td>Rynacrom</td>
<td>SW</td>
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<td>4311X</td>
<td>levocabastine 0.05% (500 microgram/mL) nasal spray, 100 actuations</td>
<td>‡1 2 ..</td>
<td>18.58</td>
<td>6.00</td>
<td>Livostin</td>
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**Corticosteroids**

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<tr>
<td>4092J</td>
<td>budesonide 64 microgram/actuation nasal spray, 120 actuations</td>
<td>‡1 .. ..</td>
<td>37.51</td>
<td>6.00</td>
<td>Budamax Aqueous</td>
<td>PM</td>
<td></td>
</tr>
</tbody>
</table>

**Other nasal preparations**

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
<th>Dispensed Price for Max. Qty $</th>
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<th>Maximum Recordable Value for Safety Net $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>4089F</td>
<td>ipratropium bromide anhydrous 21 microgram/actuation nasal spray, 180 actuations</td>
<td>‡1 5 ..</td>
<td>23.93</td>
<td>6.00</td>
<td>Atrovent Nasal Aqueous</td>
<td>BY</td>
<td></td>
</tr>
<tr>
<td>4090G</td>
<td>ipratropium bromide anhydrous 42 microgram/actuation nasal spray, 180 actuations</td>
<td>‡1 5 ..</td>
<td>30.81</td>
<td>6.00</td>
<td>Atrovent Nasal Forte</td>
<td>BY</td>
<td></td>
</tr>
</tbody>
</table>

#### NASAL DECONGESTANTS FOR SYSTEMIC USE

**Sympathomimetics**

<table>
<thead>
<tr>
<th>Code</th>
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</tr>
</thead>
<tbody>
<tr>
<td>4029C</td>
<td>pseudoephedrine hydrochloride 60 mg tablet, 12</td>
<td>1 .. ..</td>
<td>11.36</td>
<td>6.00</td>
<td>Logincin Sinus</td>
<td>QA</td>
<td></td>
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</tbody>
</table>

### COUGH AND COLD PREPARATIONS

#### EXPECTORANTS, EXCL. COMBINATIONS WITH COUGH SUPPRESSANTS

**Expectorants**

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
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<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>4074K</td>
<td>ammonium bicarbonate 25 mg/mL + senega root 25 mg/mL oral liquid, 200 mL</td>
<td>‡1 4 ..</td>
<td>9.52</td>
<td>6.00</td>
<td>Gold Cross</td>
<td>BI</td>
<td></td>
</tr>
</tbody>
</table>

### COUGH SUPPRESSANTS, EXCL. COMBINATIONS WITH EXPECTORANTS

**Opium alkaloids and derivatives**

#### PHOLCODINE

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
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<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>4071G</td>
<td>pholcodine 1 mg/mL oral liquid, 100 mL</td>
<td>‡1 2 ..</td>
<td>9.36</td>
<td>6.00</td>
<td>Gold Cross</td>
<td>BI</td>
<td></td>
</tr>
</tbody>
</table>
# RESPIRATORY SYSTEM

## ANTIHISTAMINES FOR SYSTEMIC USE

### Piperazine derivatives

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
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<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>4175R</td>
<td>cetirizine hydrochloride 10 mg tablet, 30</td>
<td>1</td>
<td>..</td>
<td>29.99</td>
<td>6.00</td>
<td>..</td>
<td>Alzene AF</td>
</tr>
<tr>
<td></td>
<td>..</td>
<td>..</td>
<td>..</td>
<td>33.21</td>
<td>6.00</td>
<td>Zilarex SZ</td>
<td></td>
</tr>
<tr>
<td></td>
<td>..</td>
<td>..</td>
<td>..</td>
<td>39.79</td>
<td>6.00</td>
<td>Zyrtec JT</td>
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</table>

### Other antihistamines for systemic use

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
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<tbody>
<tr>
<td>4238C</td>
<td>fexofenadine hydrochloride 120 mg tablet, 30</td>
<td>1</td>
<td>..</td>
<td>29.76</td>
<td>6.00</td>
<td>..</td>
<td>Xergic AF</td>
</tr>
<tr>
<td></td>
<td>..</td>
<td>..</td>
<td>..</td>
<td>35.05</td>
<td>6.00</td>
<td>Fexal SZ</td>
<td></td>
</tr>
<tr>
<td></td>
<td>..</td>
<td>..</td>
<td>..</td>
<td>47.47</td>
<td>6.00</td>
<td>Telfast 120 SW</td>
<td></td>
</tr>
<tr>
<td>4237B</td>
<td>fexofenadine hydrochloride 60 mg tablet, 20</td>
<td>3</td>
<td>..</td>
<td>*55.33</td>
<td>6.00</td>
<td>Telfast SW</td>
<td></td>
</tr>
</tbody>
</table>

| 4313B | loratadine 10 mg tablet, 30                          | 1                | ..          | 33.33                           | 6.00   | ..                                       | Allereze AF                 |
|       | ..                                                   | ..               | ..          | 43.99                           | 6.00   | Lorano SZ                                |
|       | ..                                                   | ..               | ..          | 46.26                           | 6.00   | Claratyne MK                             |
### SENSORY ORGANS

#### OPTHALMOLOGICALS

**DECONGESTANTS AND ANTIALLERGICS**

*Sympathomimetics used as decongestants*

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
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</tr>
</thead>
<tbody>
<tr>
<td>4035J</td>
<td>naphazoline hydrochloride 0.1% eye drops, 15 mL</td>
<td>‡1</td>
<td>1</td>
<td>..</td>
<td>15.43</td>
<td>6.00</td>
<td>Albalon Liquifilm</td>
</tr>
<tr>
<td>4032F</td>
<td>naphazoline hydrochloride 0.05% + antazoline phosphate 0.5% eye drops, 15 mL</td>
<td>‡1</td>
<td>1</td>
<td>..</td>
<td>15.14</td>
<td>6.00</td>
<td>Albalon-A</td>
</tr>
</tbody>
</table>

*Other antiallergics*

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
<th>No. of Rpts</th>
<th>Premium $</th>
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</thead>
<tbody>
<tr>
<td>4310W</td>
<td>levocabastine 0.05% eye drops, 4 mL</td>
<td>‡1</td>
<td>1</td>
<td>..</td>
<td>18.58</td>
<td>6.00</td>
<td>Livostin</td>
</tr>
</tbody>
</table>

#### OTHER OTOLOGICALS

*Indifferent preparations*

<table>
<thead>
<tr>
<th>Code</th>
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<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>4176T</td>
<td>carbamide peroxide 6.5% ear drops, 12 mL</td>
<td>‡1</td>
<td>..</td>
<td>..</td>
<td>16.42</td>
<td>6.00</td>
<td>Ear Clear for Ear Wax Removal</td>
</tr>
<tr>
<td>4180B</td>
<td>dichlorobenzene with chlorbutol and arachis oil</td>
<td>‡1</td>
<td>..</td>
<td>..</td>
<td>14.42</td>
<td>6.00</td>
<td>Cerumol</td>
</tr>
<tr>
<td>4199B</td>
<td>docusate sodium 0.5% (5 mg/mL) ear drops, 10 mL</td>
<td>‡1</td>
<td>..</td>
<td>..</td>
<td>14.81</td>
<td>6.00</td>
<td>Waxsol</td>
</tr>
</tbody>
</table>
### ALL OTHER THERAPEUTIC PRODUCTS

**Drugs for treatment of hyperkalemia and hyperphosphatemia**

<table>
<thead>
<tr>
<th>Code</th>
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<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>4470G</td>
<td>POLYSTYRENE SULFONATE SODIUM</td>
<td>¶1</td>
<td>2</td>
<td>..</td>
<td>71.46</td>
<td>6.00</td>
<td>Resonium-A</td>
</tr>
</tbody>
</table>

*Note: The detailed description includes: 999.3 mg/g powder, 454 g.*
REPATRIATION PHARMACEUTICAL BENEFITS SCHEME (RPBS)

**WOUND ASSESSMENT AND DRESSING IDENTIFICATION**

It is essential to define the aetiology of the wound before selecting a dressing. Recommendations are based on wound type, colour of wound base, depth of wound, and amount of exudate.

This wound chart adheres to the MOIST WOUND concept of healing and wound dressings are described below as ABSORBING or MOISTURE DONATING.

Most wound healing products are designed to remain in situ for several days, with the exception of those for infected wounds which should be changed daily. The quantities and repeats listed in the Repatriation Schedule are considered to be adequate to manage the treatment of a wound for two weeks to one month, when an assessment of the wound’s healing process should be undertaken.

**DRESSINGS**

**PINK EPITHELIALISING WOUND**

Aim: To protect and promote epithelialisation. Epithelialising wounds normally are superficial and only produce a light exudate.

(A) Covering
- Film;
- Film Island
- Gauze—Paraffin;
- Non-adherent

(B) Absorbing
- Foam (Light Exudate);
- Hydroactive (Superficial Wound—Light Exudate)
- Hydrocolloid (Superficial Wound—Light Exudate)

**RED GRANULATING WOUND**

Aims: (1) to protect the granulating tissue; (2) to encourage epithelialisation; (3) to absorb excess exudate.

**LIGHT EXUDATE:**

(A) Absorbing
- Foam (Light Exudate);
- Hydroactive (Superficial Wound—Light Exudate);
- Hydrocolloid (Superficial Wound—Light Exudate)

(B) Moisture donating
- Hydrogel—Amorphous;
- Hydrogel—Sheet

**HIGH EXUDATE:**

(A) Absorbing
- Alginate (Superficial Wound);
- Foam—Heavy Exudate;
- Hydroactive (Superficial Wound—Moderate Exudate);
- Hydrocolloid (Superficial Wound—Moderate/High Exudate)

(B) Moisture donating
- Alginate (Cavity Wound);
- Foam—Moderate Exudate (see “cavity conforming” product);
- Hydroactive (Cavity Wound);
- Hydrocolloid (Cavity Wound)

(B) Moisture donating
- Hydrogel—Amorphous

- Hydrogel—Amorphous

- Hydrogel—Sheet

- Hydrogel—Amorphous

- Alginate (Cavity Wound);
- Foam—Moderate Exudate

- Hydroactive (Cavity Wound);
- Hydrocolloid (Cavity Wound)

- Hydrogel—Amorphous

- Alginate (Cavity Wound);
- Foam—Moderate Exudate

- Hydroactive (Cavity Wound);
- Hydrocolloid (Cavity Wound)

- Hydrogel—Amorphous

- Alginate (Cavity Wound);
- Foam—Moderate Exudate

- Hydroactive (Cavity Wound);
- Hydrocolloid (Cavity Wound)
**YELLOW SLOUGHY WOUND**

Aims: (1) to remove slough; (2) to encourage granulation; (3) to absorb excess exudate.

**LIGHT EXUDATE:**

(A) Absorbing

- Cadexomer Iodine;
- Foam—Light Exudate;
- Foam with Charcoal;
- Hydroactive (Superficial Wound—Moderate Exudate);
- Hydrocolloid (Superficial Wound—Moderate Exudate)

(B) Moisture Donating

- Hydrogel—Amorphous
- Hydrogel—Sheet

**HIGH EXUDATE:**

(A) Absorbing

- Alginate (Superficial Wound);
- Cadexomer Iodine;
- Foam—Heavy Exudate;
- Hydroactive (Superficial Wound—Moderate/High Exudate);
- Hydrocolloid (Superficial Wound—Moderate/High Exudate)

(B) Moisture donating

- Hydrogel—Amorphous
- Hydrogel—Sheet

**BLACK NECROTIC WOUND**

Aim: To remove eschar by — (1) sharp debridement, e.g., scissors/scalpel and/or (2) rehydration and autolytic debridement. (These wounds usually produce a LIGHT EXUDATE.)

**DRY / LIGHT EXUDATE:**

(A) Absorbing

- Hydroactive (Superficial Wound—Light Exudate);
- Hydrocolloid (Superficial Wound—Light/Moderate Exudate)

(B) Moisture donating

- Hydrogel—Amorphous
- Hydrogel—Sheet

**INFECTED WOUNDS**

Aims: (1) to clear the infection with systemic antibiotics; (2) to absorb excess exudate; (3) to remove slough if present; (4) to decrease bacterial burden - by applying a Silver dressing or Cadexomer Iodine dressing.

**MALODOROUS WOUNDS**

Aims: (1) to clear infection if present; (2) to remove slough if present; (3) to clear colonising odour-producing bacteria in slough — by applying metronidazole gel, a Silver dressing or a Cadexomer Iodine dressing; (4) to absorb excess exudate.

Products: Activated Charcoal; Alginate with Charcoal; Foam with Charcoal; Silver dressing; Cadexomer Iodine dressing.

**MINOR SKIN TRAUMA**
Aims: (1) to stop bleeding; (2) to prevent infection; (3) to minimise the surface defect; (4) to promote epithelialisation.

ORDERING HARTMANN PRODUCTS

Hartmann wound dressings are available through HARTMANN and Independence Australia only. If you would like to order Hartmann Wound Care products, please call HARTMANN customer service on 1800 805 839 or Independence Australia on 1300 788 855.

ORDERING COLOPLAST PRODUCTS

Coloplast dressings are available via a range of distributors. However, Coloplast’s principal agreement to ensure correct RPBS Price to Pharmacy and ready supply has been secured with Independence Australia on 1300 788 855 and BrightSky on 1300 290 400. Please note that Coloplast is unable to guarantee ready supply or rebate for price differences on purchases outside these distributors.

ORDERING MOLNLYCKE HEALTHCARE PRODUCTS

Molnlycke Healthcare products are distributed through leading pharmacy distributors. To best ensure product availability at RPBS agreed prices, special arrangements have been made with API and Independence Australia Health Solutions (IAHS). IAHS orders can be placed on: Tel: 1300 788 855; or Email customerservice@independenceaustralia.com. Molnlycke Healthcare are not able to ensure product availability or pricing on listed products beyond these two suppliers.

ALL OTHER NON-THERAPEUTIC PRODUCTS

LUBRICATING AGENT

4306P lubricating agent jelly, 100 g 1 .. .. 10.47 6.00 Lubri-Gel PP

Other non-therapeutic auxiliary products

BANDAGE ABSORBENT WOOL

4653X bandage absorbent wool 10 cm x 3 m bandage, 1 1 .. .. 20.66 6.00 Surepress 650948 CC

BANDAGE CALICO

Smith & Nephew products are distributed via the three major wholesalers, API, Sigma and Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS agreed pricing from distributors other than those aforementioned.

4717G bandage calico large bandage: triangular, 1 bandage ¶1 .. .. 13.11 6.00 Handy 36361414 BV

BANDAGE COMPRESSION

Smith & Nephew products are distributed via the three major wholesalers, API, Sigma and Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS agreed pricing from distributors other than those aforementioned.

4654Y BANDAGE-COMPRESSION Bandage, short stretch, 8 cm x 2.6 m, 1 5 .. .. *73.26 6.00 Comprilan 01027-00 BV

4748X bandage compression 10 cm x 3 m bandage: high stretch, 1 bandage 5 .. .. *73.26 6.00 Surepress 650947 CC

BANDAGE COMPRESSION

Molnlycke Health Care products are distributed through leading pharmacy distributors. To best ensure product availability at the RPBS agreed prices, special arrangements have been made with API and Independence Australia Health Solutions (IAHS). IAHS orders can be placed on: Tel: 1300 788 855; or Email customerservice@independenceaustralia.com. Molnlycke Health Care is not able to ensure product availability or pricing on listed products beyond these two suppliers.

4657D bandage compression 10 cm x 3.5 m bandage: high stretch, 1 bandage 5 .. .. *78.91 6.00 Setopress 3505 MH

BANDAGE COMPRESSION

Note

Treatment of varices and oedema associated with venous disease and lymphoedema; contraindicated in arterial disease.

Note

Smith & Nephew products are distributed via the three major wholesalers, API, Sigma and Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS agreed pricing from distributors other than those aforementioned.

4654Y BANDAGE-COMPRESSION Bandage, short stretch, 8 cm x 2.6 m, 1 5 .. .. *73.26 6.00 Comprilan 01027-00 BV

4748X bandage compression 10 cm x 3 m bandage: high stretch, 1 bandage 5 .. .. *73.26 6.00 Surepress 650947 CC

BANDAGE COMPRESSION

Note

Treatment of varices and oedema associated with venous disease and lymphoedema; contraindicated in arterial disease.

Note

Molnlycke Health Care products are distributed through leading pharmacy distributors. To best ensure product availability at the RPBS agreed prices, special arrangements have been made with API and Independence Australia Health Solutions (IAHS). IAHS orders can be placed on: Tel: 1300 788 855; or Email customerservice@independenceaustralia.com. Molnlycke Health Care is not able to ensure product availability or pricing on listed products beyond these two suppliers.

4657D bandage compression 10 cm x 3.5 m bandage: high stretch, 1 bandage 5 .. .. *78.91 6.00 Setopress 3505 MH

BANDAGE COMPRESSION

Note
<table>
<thead>
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</tr>
</thead>
<tbody>
<tr>
<td>4598B</td>
<td>bandage compression bandage: four layer, 1 bandage</td>
<td>5</td>
<td>..</td>
<td>..</td>
<td>*153.56</td>
<td>6.00</td>
<td>Profore Lite 66050415 SN</td>
</tr>
<tr>
<td>4658E</td>
<td>bandage compression bandage: four layer, 1 bandage</td>
<td>5</td>
<td>..</td>
<td>..</td>
<td>*225.56</td>
<td>6.00</td>
<td>Profore 66050016 SN</td>
</tr>
</tbody>
</table>

**VARIOUS**

Treatment of varices and oedema associated with venous disease and lymphoedema; contraindicated in arterial disease.

**Note**

Smith & Nephew products are distributed via the three major wholesalers, API, Sigma, and Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS pricing from distributors other than those aforementioned.

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<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>4050E</td>
<td>bandage compression bandage: two layer, 1 bandage</td>
<td>1</td>
<td>..</td>
<td>..</td>
<td>43.02</td>
<td>6.00</td>
<td>Coban 2 MM</td>
</tr>
</tbody>
</table>

**BANDAGE COMPRESSION**

**Restricted benefit**

Initial treatment of venous ulcers

**Restricted benefit**

Continuation of treatment of venous ulcers where patient's ability to tolerate dressing has been demonstrated

**Note**

Treatment of varices and oedema associated with venous disease and lymphoedema; contraindicated in arterial disease.

**Note**

Bandage can be left in situ for up to 7 days as per manufacturer's instructions.

<table>
<thead>
<tr>
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</tr>
</thead>
<tbody>
<tr>
<td>4813H</td>
<td>bandage retention cohesive heavy 10 cm x 1.3 m bandage, 1</td>
<td>2</td>
<td>..</td>
<td>..</td>
<td>*21.42</td>
<td>6.00</td>
<td>Peg 7423 MM</td>
</tr>
<tr>
<td>4660G</td>
<td>bandage retention cohesive heavy 10 cm x 2 m bandage, 1</td>
<td>2</td>
<td>..</td>
<td>..</td>
<td>*19.70</td>
<td>6.00</td>
<td>Coban 1584 MM</td>
</tr>
<tr>
<td>4814J</td>
<td>bandage retention cohesive heavy 15 cm x 1.3 m bandage, 1</td>
<td>2</td>
<td>..</td>
<td>..</td>
<td>*28.52</td>
<td>6.00</td>
<td>Peg 7425 MM</td>
</tr>
<tr>
<td>4811F</td>
<td>bandage retention cohesive heavy 5 cm x 1.3 m bandage, 1</td>
<td>2</td>
<td>..</td>
<td>..</td>
<td>*14.36</td>
<td>6.00</td>
<td>Peg 7420 MM</td>
</tr>
<tr>
<td>4812G</td>
<td>bandage retention cohesive heavy 7.5 cm x 1.3 m bandage, 1</td>
<td>2</td>
<td>..</td>
<td>..</td>
<td>*17.64</td>
<td>6.00</td>
<td>Peg 7422 MM</td>
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**BANDAGE RETENTION COHESIVE HEAVY**

**Note**

Smith & Nephew products are distributed via the three major wholesalers, API, Sigma, and Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS agreed pricing from distributors other than those aforementioned.

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<tbody>
<tr>
<td>4662J</td>
<td>bandage retention cohesive light 10 cm x 2 m bandage, 1</td>
<td>2</td>
<td>..</td>
<td>..</td>
<td>*30.38</td>
<td>6.00</td>
<td>Handygauze Cohesive 8635 BV</td>
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<td>4718H</td>
<td>bandage retention cohesive light 2.5 cm x 2 m bandage, 2</td>
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<td>..</td>
<td>13.23</td>
<td>6.00</td>
<td>Handygauze Cohesive 8631 BV</td>
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<td>4719J</td>
<td>bandage retention cohesive light 6 cm x 2 m bandage, 1</td>
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<td>..</td>
<td>..</td>
<td>*15.74</td>
<td>6.00</td>
<td>Handygauze Cohesive 8633 BV</td>
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**BANDAGE RETENTION COHESIVE LIGHT**

**Note**

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<td>4729X</td>
<td>bandage retention cotton crepe 10 cm x 2.3 m bandage, 1</td>
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<td>..</td>
<td>*25.72</td>
<td>6.00</td>
<td>Telfa 8254F KE</td>
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<tr>
<td>4727T</td>
<td>bandage retention cotton crepe 5 cm x 2.3 m bandage, 1</td>
<td>2</td>
<td>..</td>
<td>..</td>
<td>*17.76</td>
<td>6.00</td>
<td>Tensocrepe 36301001 BV KE</td>
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<tr>
<td>4728W</td>
<td>bandage retention cotton crepe 7.5 cm x 2.3 m bandage, 1</td>
<td>2</td>
<td>..</td>
<td>..</td>
<td>*22.56</td>
<td>6.00</td>
<td>Telfa 8253F KE</td>
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**BANDAGE RETENTION COTTON CREPE**

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<tr>
<td>4730X</td>
<td>bandage retention crepe 10 cm x 2.3 m bandage, 1</td>
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<td>*29.90</td>
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<tr>
<td>4731T</td>
<td>bandage retention crepe 5 cm x 2.3 m bandage, 1</td>
<td>2</td>
<td>..</td>
<td>..</td>
<td>*19.64</td>
<td>6.00</td>
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**BANDAGE TUBULAR**

**Note**

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<tr>
<td>4859R</td>
<td>bandage tubular 10 cm x 1 m bandage, 1</td>
<td>†1</td>
<td>..</td>
<td>..</td>
<td>15.32</td>
<td>Tubigrip F 1548 MH</td>
</tr>
<tr>
<td>4855M</td>
<td>bandage tubular 6.25 cm x 1 m bandage, 1</td>
<td>†1</td>
<td>..</td>
<td>..</td>
<td>15.32</td>
<td>Tubigrip B 1520 MH</td>
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<tr>
<td>4856N</td>
<td>bandage tubular 6.75 cm x 1 m bandage, 1</td>
<td>†1</td>
<td>..</td>
<td>..</td>
<td>15.32</td>
<td>Tubigrip C 1545 MH</td>
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<tr>
<td>4857P</td>
<td>bandage tubular 7.5 cm x 1 m bandage, 1</td>
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<td>..</td>
<td>..</td>
<td>15.32</td>
<td>Tubigrip D 1546 MH</td>
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<tr>
<td>4858Q</td>
<td>bandage tubular 8.75 cm x 1 m bandage, 1</td>
<td>†1</td>
<td>..</td>
<td>..</td>
<td>15.32</td>
<td>Tubigrip E 1547 MH</td>
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### BANDAGE TUBULAR

#### BANDAGE TUBULAR FINGER

Complete pack including applicator, 1

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<tr>
<td>4798M</td>
<td>BANDAGE-TUBULAR (FINGER)</td>
<td>†1</td>
<td>..</td>
<td>..</td>
<td>18.11</td>
<td>Tubegauz 0501633 SS</td>
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### BANDAGE TUBULAR LIGHT WEIGHT

#### Note

Molnlycke Health Care products are distributed through leading pharmacy distributors. To best ensure product availability at the RPBS agreed prices, special arrangements have been made with API and Independence Australia Health Solutions (IAHS). IAHS orders can be placed on: Tel: 1300 788 855; or Email: customerservice@independenceaustralia.com. Molnlycke Health Care is not able to ensure product availability or pricing on listed products beyond these two suppliers.

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<tr>
<td>4673Y</td>
<td>bandage tubular light weight 10 m</td>
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<td>28.47</td>
<td>Tubifast 2438 MH</td>
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<td>4672X</td>
<td>bandage tubular light weight 10 m</td>
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<td>..</td>
<td>..</td>
<td>27.06</td>
<td>Tubifast 2436 MH</td>
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<tr>
<td>4671W</td>
<td>bandage tubular light weight 10 m</td>
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<td>..</td>
<td>..</td>
<td>23.10</td>
<td>Tubifast 2434 MH</td>
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### BANDAGE TUBULAR LONG STOCKING

#### Note

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<tr>
<td>4675C</td>
<td>bandage tubular long stocking bandage: XX/large size, 1 bandage</td>
<td>2</td>
<td>..</td>
<td>..</td>
<td>*37.48</td>
<td>Tubigrip 1486 MH</td>
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<tr>
<td>4799N</td>
<td>bandage tubular long stocking bandage: large size, 1 bandage</td>
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<td>..</td>
<td>..</td>
<td>*37.46</td>
<td>Tubigrip 1484 MH</td>
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<tr>
<td>4797L</td>
<td>bandage tubular long stocking bandage: medium size, 1 bandage</td>
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<td>..</td>
<td>..</td>
<td>*37.46</td>
<td>Tubigrip 1483 MH</td>
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<tr>
<td>4674B</td>
<td>bandage tubular long stocking bandage: small size, 1 bandage</td>
<td>2</td>
<td>..</td>
<td>..</td>
<td>*37.46</td>
<td>Tubigrip 1482 MH</td>
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### BANDAGE TUBULAR SHORT STOCKING

#### Note

Molnlycke Health Care products are distributed through leading pharmacy distributors. To best ensure product availability at the RPBS agreed prices, special arrangements have been made with API and Independence Australia Health Solutions (IAHS). IAHS orders can be placed on: Tel: 1300 788 855; or Email: customerservice@independenceaustralia.com. Molnlycke Health Care is not able to ensure product availability or pricing on listed products beyond these two suppliers.

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<td>4816L</td>
<td>bandage tubular short stocking bandage: large D/E size, 1 bandage</td>
<td>2</td>
<td>..</td>
<td>..</td>
<td>*25.72</td>
<td>Tubigrip 1481 MH</td>
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<tr>
<td>4815K</td>
<td>bandage tubular short stocking bandage: large D/E size, 1 bandage</td>
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<td>..</td>
<td>*25.72</td>
<td>Tubigrip 1480 MH</td>
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<tr>
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<td>4661H</td>
<td>bandage: medium C/D size, 1 bandage bandage tubular short stocking bandage: small B/C size, 1 bandage</td>
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<td>..</td>
<td>25.72</td>
<td>Tubigrip 1479 MH</td>
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<td>4670T</td>
<td>bandage zinc paste 10 cm x 9.1 m bandage, 1</td>
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<td>3</td>
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<td>29.12</td>
<td>Flexidress 650941 CC</td>
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<tr>
<td>4669R</td>
<td>bandage zinc paste 7.5 cm x 6 m bandage, 1</td>
<td>2</td>
<td>3</td>
<td>..</td>
<td>30.00</td>
<td>Steripaste 3610 MH</td>
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<tr>
<td>4750B</td>
<td>bandage zinc paste 7.5 cm x 6 m bandage, 1</td>
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<td>3</td>
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<td>79.12</td>
<td>Viscopaste 4948 SN</td>
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<tr>
<td>4760M</td>
<td>bandage zinc paste 80 cm (stockings) bandage, 4</td>
<td>1‡</td>
<td>3</td>
<td>..</td>
<td>91.26</td>
<td>ZipZoc 66000747 SN</td>
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<tr>
<td>2525X</td>
<td>betaine 0.1% (40 microgram/40 mL) + polyaminopropyl biguanide 0.1% (40 microgram/40 mL), 6 x 40 mL ampoules</td>
<td>1</td>
<td>..</td>
<td>..</td>
<td>27.01</td>
<td>Prontosan Wound Irrigation Solution BR</td>
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<tr>
<td>4937W</td>
<td>dressing with CADEXOMER IODINE Sheets 17 g (10 cm x 8 cm), 2, 1</td>
<td>1‡</td>
<td>..</td>
<td>..</td>
<td>157.31</td>
<td>Iodosorb 66051360 SN</td>
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<tr>
<td>4935R</td>
<td>dressing with CADEXOMER IODINE Sheets 5 g (6 cm x 4 cm), 5, 1</td>
<td>1‡</td>
<td>2</td>
<td>..</td>
<td>103.34</td>
<td>Iodosorb 66051330 SN</td>
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<td>4931M</td>
<td>cadexomer-iodine 3 g powder: dusting sterile, 7 x 3 g sachets</td>
<td>1‡</td>
<td>2</td>
<td>..</td>
<td>67.95</td>
<td>Iodosorb Powder 66051070 SN</td>
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<tr>
<td>4933P</td>
<td>cadexomer-iodine 50% (500 mg/g) ointment, 2 x 20 g tubes</td>
<td>1‡</td>
<td>2</td>
<td>..</td>
<td>108.30</td>
<td>Iodosorb Ointment 66051230 SN</td>
</tr>
<tr>
<td>4932N</td>
<td>cadexomer-iodine 50% (500 mg/g) ointment, 4 x 10 g tubes</td>
<td>1‡</td>
<td>2</td>
<td>..</td>
<td>109.31</td>
<td>Iodosorb Ointment 66051240 SN</td>
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<tr>
<td>4936T</td>
<td>cadexomer-iodine 8 cm x 6 cm dressing, 3 x 10 g sheets</td>
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<td>2</td>
<td>..</td>
<td>149.27</td>
<td>Iodosorb 66051340 SN</td>
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<td>dressing activated charcoal malodorous wound 10 cm x 10 cm dressing, 10</td>
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<td>79.32</td>
<td>CarboFLEX 403202 CC</td>
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<td>dressing activated charcoal malodorous wound 10.5 cm x 10.5 cm dressing, 1</td>
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<td>..</td>
<td>101.26</td>
<td>Actisorb Plus MAP105 JJ</td>
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<td>4743P</td>
<td>dressing activated charcoal malodorous wound 15 cm x 20 cm dressing. 5</td>
<td>1</td>
<td>..</td>
<td>..</td>
<td>90.21</td>
<td>6.00</td>
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</tbody>
</table>

**DRESSING ALGINATE CAVITY WOUND**

*Note*

This dressing should be used only on moderately to heavily exuding wounds and should remain in place until saturated or for a maximum of 3 days.

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<tr>
<td>4832H</td>
<td>DRESSING-ALGINATE (CAVITY WOUND) Rope 2 g, 1</td>
<td>10</td>
<td>..</td>
<td>..</td>
<td>*109.46</td>
<td>6.00</td>
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<tr>
<td>1905G</td>
<td>DRESSING-ALGINATE (CAVITY WOUND) Rope 2 g, 5</td>
<td>2</td>
<td>..</td>
<td>..</td>
<td>*115.60</td>
<td>6.00</td>
</tr>
</tbody>
</table>

**DRESSING ALGINATE CAVITY WOUND**

*Note*

This dressing should be used only on moderately to heavily exuding wounds and should remain in place until saturated or for a maximum of 3 days.

*Note*

Coloplast dressings are available via a range of distributors. However, Coloplast’s principal agreement to ensure correct RPBS Price to Pharmacy and ready supply has been secured with Independence Australia on 1300 788 855 and BrightSky on 1300 290 400. Please note that Coloplast is unable to guarantee ready supply or rebate for price differences on purchases outside these distributors.

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<td>4682K</td>
<td>dressing alginate cavity wound 2 g (40 cm) rope, 6 x 2 g</td>
<td>2</td>
<td>..</td>
<td>..</td>
<td>*138.06</td>
<td>6.00</td>
</tr>
</tbody>
</table>

**DRESSING ALGINATE SUPERFICIAL WOUND**

*Note*

This dressing should be used only on moderately to heavily exuding wounds and should remain in place until saturated or for a maximum of 3 days.

*Note*

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<tr>
<td>4831G</td>
<td>dressing alginate superficial wound 10 cm x 10 cm dressing. 1</td>
<td>10</td>
<td>1</td>
<td>..</td>
<td>*84.76</td>
<td>6.00</td>
</tr>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>*90.46</td>
<td>6.00</td>
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<tr>
<td>4684M</td>
<td>dressing alginate superficial wound 5 cm x 5 cm dressing. 1</td>
<td>10</td>
<td>1</td>
<td>..</td>
<td>*47.26</td>
<td>6.00</td>
</tr>
</tbody>
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**DRESSING ALGINATE SUPERFICIAL WOUND**

*Note*

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*Note*

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<tr>
<td>4700J</td>
<td>dressing alginate superficial wound 10 cm x 10 cm dressing. 10</td>
<td>1</td>
<td>1</td>
<td>..</td>
<td>105.49</td>
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<td>dressing alginate superficial wound 15 cm x 20 cm dressing. 10</td>
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<td>251.87</td>
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<td>4699H</td>
<td>dressing alginate superficial wound 5 cm x 5 cm dressing. 10</td>
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<td>1</td>
<td>..</td>
<td>49.74</td>
<td>6.00</td>
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**DRESSING ALGINATE SUPERFICIAL WOUND**

*Note*

This dressing should be used only on moderately to heavily exuding wounds and should remain in place until saturated or for a maximum of 3 days.

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<tr>
<td>4683L</td>
<td>dressing alginate superficial wound 7.5 cm x 12 cm dressing. 10</td>
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<td>..</td>
<td>91.42</td>
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</tbody>
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**DRESSING FILM**

*Note*

Smith & Nephew products are distributed via the three major wholesalers, API, Sigma & Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS pricing from distributors other than those aforementioned.

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### DRESSING FILM

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<td>4687Q</td>
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<td>4688R</td>
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<td>*31.00</td>
<td>6.00</td>
<td>Tegaderm Transparent 1628 MM</td>
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<tr>
<td>4686P</td>
<td>dressing film 6 cm x 7 cm dressing, 8</td>
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<td>..</td>
<td>15.98</td>
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**DRESSING FILM ISLAND**

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<tr>
<td>4689T</td>
<td>dressing film island 5 cm x 7 cm dressing, 1</td>
<td>10</td>
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<td>..</td>
<td>*16.56</td>
<td>6.00</td>
<td>Tegaderm Transparent Island 3582 MM</td>
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<tr>
<td>4690W</td>
<td>dressing film island 9 cm x 10 cm dressing, 1</td>
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<td>..</td>
<td>..</td>
<td>*28.06</td>
<td>6.00</td>
<td>Tegaderm Transparent Island 3586 MM</td>
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**DRESSING FILM ISLAND**

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- 4898T dressing film island 5 cm x 7.2 cm dressing, 5                                    | 2                | ..          | ..        | 28.36                          | 6.00                                     | Cutfilm Plus 36361370 SN            |
- 4899W dressing film island 8 cm x 10 cm dressing, 5                                    | 2                | ..          | ..        | 44.46                          | 6.00                                     | Cutfilm Plus 36361371 SN            |

**DRESSING FOAM HEAVY EXUDATE**

**Note**
- This dressing should remain in place until saturated or up to a maximum of 7 days. Allow a minimum of 2 cm to 3 cm in excess of the wound size of the dressing around the wound.

**Note**
- Smith & Nephew products are distributed via the three major wholesalers, API, Sigma & Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS pricing from distributors other than those aforementioned.

- 4795J dressing foam heavy exudate 10 cm x 10 cm dressing, 10                            | ‡1               | 1           | ..        | 127.50                        | 6.00                                     | Allevyn 66007637 SN                 |

**DRESSING FOAM MODERATE EXUDATE**

**Note**
- This dressing should remain in place until saturated or up to a maximum of 7 days. Allow a minimum of 2 cm to 3 cm in excess of the wound size of the dressing around the wound.

**Note**
- Smith & Nephew products are distributed via the three major wholesalers, API, Sigma & Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS pricing from distributors other than those aforementioned.

- 4590N dressing foam moderate exudate 12.5 cm x 12.5 cm dressing, 10                     | ‡1               | ..          | ..        | 132.11                        | 6.00                                     | Allevyn Adhesive 66000044 SN        |

**DRESSING FOAM MODERATE EXUDATE**

**Note**
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- 4694C dressing foam moderate exudate cavity conforming foam, 1 x 20 g sachet             | 1                | 1           | ..        | 95.09                          | 6.00                                     | Cavicare 4563 SN                   |

**DRESSING FOAM WITH SILICONE**

**Note**
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- 10017F dressing foam with silicone 10.3 cm x 10.3 cm dressing, 10                         | ‡1               | ..          | ..        | 55.40                          | 6.00                                     | Allevyn Life 66801067 SN            |
- 10029W dressing foam with silicone 12.9 cm x 12.9 cm dressing, 10                         | ‡1               | ..          | ..        | 79.61                          | 6.00                                     | Allevyn Life 66801068 SN            |
VARIOUS

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<td>220.75</td>
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**DRESSING FOAM WITH SILICONE AND SILVER**

*Authority required*

Wound critical colonisation or chronic wounds that have not responded to conventional dressings

**Clinical criteria:**

- Patient must have a wound where there is evidence of critical colonisation; OR
- Patient must have a well-assessed chronic wound that has not responded to conventional dressings.

**Note**

Molnlycke Health Care products are distributed through leading pharmacy distributors. To best ensure product availability at the RPBS agreed prices, special arrangements have been made with API and Independence Australia Health Solutions (IAHS). IAHS orders can be placed on: Tel: 1300 788 855; or Email: customerservice@independenceaustralia.com. Molnlycke Health Care is not able to ensure product availability or pricing on listed products beyond these two suppliers.

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<td>2470B</td>
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<td>Mepilex Border Ag MH</td>
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</tbody>
</table>

**DRESSING FOAM WITH SILICONE HEAVY EXUDATE**

*Note*

Smith & Nephew products are distributed via the three major wholesalers, API, Sigma & Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS pricing from distributors other than those aforementioned.

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<td>51.71</td>
<td>6.00</td>
<td>Allevyn Gentle Border 66800269 SN</td>
</tr>
</tbody>
</table>

**DRESSING FOAM WITH SILICONE HEAVY EXUDATE**

*Note*

Molnlycke Healthcare products are distributed through leading pharmacy distributors. To best ensure product availability at RPBS agreed prices, special arrangements have been made with API and Independence Australia Health Solutions (IAHS). IAHS orders can be placed on: Tel: 1300 788 855; or Email: customerservice@independenceaustralia.com. Molnlycke Healthcare are not able to ensure product availability or pricing on listed products beyond these two suppliers.

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<td>6.00</td>
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<td>4642H</td>
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<td>31.11</td>
<td>6.00</td>
<td>Mepilex Border 295200 MH</td>
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**DRESSING FOAM WITH SILICONE LIGHT EXUDATE**

*Note*

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<tr>
<td>4645L</td>
<td>dressing foam with silicone light exudate 10 cm x 10 cm dressing, 5</td>
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<tr>
<td>4644K</td>
<td>dressing foam with silicone light exudate 6 cm x 8.5 cm dressing, 5</td>
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<td>..</td>
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<td>28.40</td>
<td>6.00</td>
<td>Mepilex Lite 284000 MH</td>
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**DRESSING FOAM WITH SILICONE MODERATE EXUDATE**

*Note*

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<td>4626L</td>
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<tr>
<td>4255Y</td>
<td>dressing foam with silver 10 cm x 10 cm dressing, 10</td>
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**DRESSING GAUZE ABSORBENT**

**Note**

Smith & Nephew products are distributed via the three major wholesalers, API, Sigma and Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS pricing from distributors other than those aforementioned.

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<td>4708T</td>
<td>dressing gauze absorbent 10 cm x 10 cm pad, 100</td>
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<td>Handy 71117-06</td>
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<td>4707R</td>
<td>dressing gauze absorbent 5 cm x 5 cm pad, 100</td>
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<td>14.79</td>
<td>6.00</td>
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**DRESSING GAUZE EYE**

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<tr>
<td>4768Y</td>
<td>dressing gauze eye pad, 12</td>
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<td>13.17</td>
<td>6.00</td>
<td>Curity 4112</td>
<td>KE</td>
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**DRESSING GAUZE PARAFFIN**

**Note**

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<tr>
<td>4759L</td>
<td>dressing gauze paraffin 10 cm x 10 cm dressing, 10</td>
<td>‡1</td>
<td>..</td>
<td>21.26</td>
<td>6.00</td>
<td>Jelonet 7404</td>
<td>SN</td>
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**DRESSING GAUZE PARAFFIN WITH CHLORHEXIDINE ACETATE**

**Note**

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<tr>
<td>4845B</td>
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<td>2</td>
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<td>6.00</td>
<td>Bactigras 7457</td>
<td>SN</td>
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**DRESSING HYDROACTIVE CAVITY WOUND**

**Note**

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<td>DRESSING-HYDROACTIVE DEBRIDEMENT (DEBRIDEMENT) Dressings 4 cm, 10, 1</td>
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<td>115.58</td>
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<td>4692Y</td>
<td>Dressing hydroactive superficial wound high exudate semi-permeable absorbent foam 10 cm x 10 cm (foam alternative) dressing, 10</td>
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<td>..</td>
<td>55.24</td>
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<tr>
<td>4695D</td>
<td>Dressing hydroactive superficial wound high exudate semi-permeable absorbent foam 11 cm x 11 cm dressing: island, 10 dressings</td>
<td>¶1 .. ..</td>
<td>..</td>
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<td>6.00</td>
<td>Tielle MTL101E JJ</td>
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<tr>
<td>4693B</td>
<td>Dressing hydroactive superficial wound high exudate semi-permeable absorbent foam 15 cm x 18 cm (foam alternative) dressing, 5</td>
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<td>72.06</td>
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<td>4696E</td>
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**DRESSING HYDROACTIVE SUPERFICIAL WOUND LIGHT EXUDATE**

*Note*
Smith & Nephew products are distributed via the three major wholesalers, API, Sigma & Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS pricing from distributors other than those aforementioned.

**DRESSING HYDROACTIVE SUPERFICIAL WOUND MODERATE EXUDATE**

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<td>4886E</td>
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<td>4885D</td>
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<td>50.93</td>
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<td>Cutinova Hydro 66047441 SN</td>
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**DRESSING HYDROCOLLOID CAVITY WOUND**

*Note*

This dressing should remain in place until saturated or strike through occurs for a maximum of 7 days.

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<td>4896Q</td>
<td>dressing hydrocolloid cavity wound paste, 30 g</td>
<td>10</td>
<td>..</td>
<td>..</td>
<td>*145.46</td>
<td>6.00</td>
<td>DuoDERM Paste H7930 CC</td>
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**DRESSING HYDROCOLLOID CAVITY WOUND**

*Note*

This dressing should remain in place until saturated or strike through occurs for a maximum of 7 days.

*Note*

Coloplast dressings are available via a range of distributors. However, Coloplast’s principal agreement to ensure correct RPBS Price to Pharmacy and ready supply has been secured with Independence Australia on 1300 788 855 and BrightSky on 1300 290 400. Please note that Coloplast is unable to guarantee ready supply or rebate for price differences on purchases outside these distributors.

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<tr>
<td>4895P</td>
<td>dressing hydrocolloid cavity wound paste, 50 g</td>
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<td>3</td>
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<td>*43.56</td>
<td>6.00</td>
<td>Comfeel Paste 4701 CT</td>
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**DRESSING HYDROCOLLOID SUPERFICIAL WOUND LIGHT EXUDATE**

*Note*

This dressing should be applied to a thickness of 3 mm to 5 mm. It should be covered with a hydrocolloid dressing and may be left in place for up to 7 days.

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<td>4907G</td>
<td>dressing hydrocolloid superficial wound light exudate 10 cm x 10 cm dressing, 10</td>
<td>¶1</td>
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<td>72.06</td>
<td>6.00</td>
<td>DuoDERM Extra Thin H7955 CC</td>
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**DRESSING HYDROCOLLOID SUPERFICIAL WOUND LIGHT EXUDATE**

*Note*

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<td>4888G</td>
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<td>42.06</td>
<td>6.00</td>
<td>Comfeel Plus Transparent 3530 CT</td>
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<td>4889H</td>
<td>dressing hydrocolloid superficial wound light exudate 9 cm x 14 cm dressing, 10</td>
<td>¶1</td>
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<td>84.86</td>
<td>6.00</td>
<td>Comfeel Plus Transparent 3536 CT</td>
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**DRESSING HYDROCOLLOID SUPERFICIAL WOUND LIGHT EXUDATE**

*Note*

This dressing should be applied to a thickness of 3 mm to 5 mm. It should be covered with a hydrocolloid dressing and may be left in place for up to 7 days.

*Note*

Hartmann wound dressings are available through HARTMANN and Independence Australia only. If you would like to order Hartmann Wound Care products, please call HARTMANN customer service on 1800 805 839 or Independence Australia on 1300 788 855.

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<td>4947J</td>
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<td>48.49</td>
<td>6.00</td>
<td>Hydrocoll Thin 900758 HR</td>
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**DRESSING HYDROCOLLOID SUPERFICIAL WOUND MODERATE EXUDATE**

*Note*

This dressing should remain in place until saturated or strike through occurs for a maximum of 7 days.

*Note*
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<tr>
<td>4923D</td>
<td>DRESSING-HYDROCOLLOID (SUPERFICIAL WOUND-MODERATE EXUDATE) Dressings with alginate</td>
<td>‡1 1 ..</td>
<td>82.34</td>
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<td>Comfeel Plus Ulcer Dressing 3110</td>
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<tr>
<td>4679G</td>
<td>dressing hydrocolloid superficial wound moderate exudate 10 cm (round) dressing, 1</td>
<td>5 .. ..</td>
<td>*59.96</td>
<td>6.00</td>
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<td>4678F</td>
<td>dressing hydrocolloid superficial wound moderate exudate 7 cm (butterfly shape) dressing, 1</td>
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<td>4945G</td>
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<td>6.00</td>
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<td>4946H</td>
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<td>2777F</td>
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<td>2803M</td>
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<tr>
<td>4698G</td>
<td>dressing hydrofibre alternate to alginate 2 g (30 cm) rope, 5 x 2 g</td>
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<td>6.00</td>
<td>Aquacel 403770</td>
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4923D

DRESSING HYDROFIBRE ALTERNATE TO ALGINATES

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4945G

DRESSING HYDROFIBRE ALTERNATE TO ALGINATES

Note

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4946H

DRESSING HYDROFIBRE ALTERNATE TO ALGINATES

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2777F

DRESSING HYDROFIBRE ALTERNATE TO ALGINATES

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2486W

DRESSING HYDROFIBRE GELLING FIBRE

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2486W

DRESSING HYDROFIBRE GELLING FIBRE

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2445Q

DRESSING HYDROFIBRE GELLING FIBRE

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2445Q

DRESSING HYDROFIBRE GELLING FIBRE

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2445Q

DRESSING HYDROFIBRE GELLING FIBRE

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2445Q

DRESSING HYDROFIBRE GELLING FIBRE

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<td>10097K</td>
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<td>279.45</td>
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<td>dressing hydrofibre with silver 2 cm x 45 cm rope, 5</td>
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<td>dressing hydrogel amorphous gel, 10 x 15 g tubes</td>
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<td>6.00</td>
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<td>dressing hydrogel amorphous gel, 25 g</td>
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<td>..</td>
<td>*66.56</td>
<td>6.00</td>
<td>Intrasite Gel 7313 SN</td>
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<tr>
<td>4599C</td>
<td>dressing hydrogel amorphous gel, 50 g</td>
<td>3</td>
<td>3</td>
<td>..</td>
<td>*30.52</td>
<td>6.00</td>
<td>SoloSite Gel 36361338 SN</td>
</tr>
<tr>
<td>4913N</td>
<td>dressing hydrogel amorphous gel, 3 x 30 g tubes</td>
<td>3</td>
<td>1</td>
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<td>*97.45</td>
<td>6.00</td>
<td>DuoDERM Gel H7987 CC</td>
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<tr>
<td>4914P</td>
<td>dressing hydrogel amorphous gel, 50 g</td>
<td>3</td>
<td>3</td>
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<td>*33.46</td>
<td>6.00</td>
<td>Solugel 10336 JJ</td>
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<tr>
<td>2533H</td>
<td>dressing hydrogel foam 10 cm x 10 cm dressing, 10</td>
<td>1</td>
<td>..</td>
<td>..</td>
<td>79.79</td>
<td>6.00</td>
<td>Sorbact Foam Dressing 98310 QL</td>
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<tr>
<td>2512F</td>
<td>dressing hydrogel ribbon 1 cm x 50 cm dressing, 20</td>
<td>1</td>
<td>..</td>
<td>..</td>
<td>118.23</td>
<td>6.00</td>
<td>Sorbact Ribbon Gauze 98118 QL</td>
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<tr>
<td>2529D</td>
<td>dressing hydrogel ribbon 5 cm x 200 cm dressing, 10</td>
<td>1</td>
<td>..</td>
<td>..</td>
<td>114.38</td>
<td>6.00</td>
<td>Sorbact Ribbon Gauze 98120 QL</td>
</tr>
</tbody>
</table>
VARIOUS

DRESSING HYDROGEL SHEET

**Note**
This dressing should be applied to a thickness of 3 mm to 5 mm and remain in situ in infected wounds for 24 hours and in clean wounds for up to 3 days. It should be covered with a secondary dressing such as foam or film. It should not be covered with gauze or combine.

**Note**
Hartmann wound dressings are available through HARTMANN and Independence Australia only. If you would like to order Hartmann Wound Care products, please call HARTMANN customer service on 1800 805 839 or Independence Australia on 1300 788 855.

<table>
<thead>
<tr>
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<th>Name, Restriction, Manner of Administration and Form</th>
<th>Max. Qty (Packs)</th>
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<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>4806Y</td>
<td>dressing hydrogel sheet 10 cm x 10 cm dressing, 5</td>
<td>2</td>
<td>..</td>
<td>*53.62</td>
<td>6.00</td>
<td>Aquaclear 900796 HR</td>
</tr>
<tr>
<td>4911L</td>
<td>dressing hydrogel sheet 9.5 cm x 10.2 cm dressing, 5</td>
<td>2</td>
<td>..</td>
<td>*83.54</td>
<td>6.00</td>
<td>Nu-Gel 2497 JJ</td>
</tr>
</tbody>
</table>

DRESSING NON ADHERENT

**Note**
Molnlycke Healthcare products are distributed through leading pharmacy distributors. To best ensure product availability at RPBS agreed prices, special arrangements have been made with API and Independence Australia Health Solutions (IAHS). IAHS orders can be placed on: Tel: 1300 788 855; or Email customer service@independenceaustralia.com. Molnlycke Healthcare are not able to ensure product availability or pricing on listed products beyond these two suppliers.

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</thead>
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<tr>
<td>4243H</td>
<td>DRESSING SELF ADHESIVE NON-ADHERENT DRY ABSORBENT</td>
<td>‡1</td>
<td>..</td>
<td>63.96</td>
<td>6.00</td>
<td>Mepitel 290510 MH</td>
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<tr>
<td>4244J</td>
<td>DRESSING SELF ADHESIVE NON-ADHERENT DRY ABSORBENT</td>
<td>‡1</td>
<td>..</td>
<td>107.96</td>
<td>6.00</td>
<td>Mepitel 290710 MH</td>
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DRESSING NON ADHERENT

**Note**
Smith & Nephew products are distributed via the three major wholesalers, API, Sigma & Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS pricing from distributors other than those aforementioned.

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<tr>
<td>4861W</td>
<td>dressing non adherent 10 cm x 10 cm dressing, 10</td>
<td>‡1</td>
<td>..</td>
<td>36.03</td>
<td>6.00</td>
<td>Melolin 66974933 SN</td>
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<tr>
<td>4862X</td>
<td>dressing non adherent 10 cm x 10 cm dressing, 5</td>
<td>2</td>
<td>..</td>
<td>*24.64</td>
<td>6.00</td>
<td>Cutilin Non-Stick Wound Pad 36361375 SN</td>
</tr>
<tr>
<td>4819P</td>
<td>dressing non adherent 5 cm x 5 cm dressing, 5</td>
<td>2</td>
<td>..</td>
<td>*15.60</td>
<td>6.00</td>
<td>Cutilin Non-Stick Wound Pad 36361374 SN</td>
</tr>
<tr>
<td>4860T</td>
<td>dressing non adherent 5 cm x 5 cm dressing, 5</td>
<td>2</td>
<td>..</td>
<td>*16.52</td>
<td>6.00</td>
<td>Melolin 36361357 SN</td>
</tr>
<tr>
<td>4755G</td>
<td>dressing non adherent 5 cm x 7.5 cm dressing, 10</td>
<td>‡1</td>
<td>..</td>
<td>11.36</td>
<td>6.00</td>
<td>Telfa 1970C KE</td>
</tr>
<tr>
<td>4758K</td>
<td>dressing non adherent 7.5 cm x 10 cm self adhesive dressing, 6</td>
<td>‡1</td>
<td>..</td>
<td>11.57</td>
<td>6.00</td>
<td>Telfa 2140C KE</td>
</tr>
<tr>
<td>4844Y</td>
<td>dressing non adherent 7.5 cm x 10 cm self adhesive dressing, 6</td>
<td>‡1</td>
<td>2</td>
<td>12.36</td>
<td>6.00</td>
<td>Telfa 7650C KE</td>
</tr>
</tbody>
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DRESSING NON ADHERENT

**Note**
Hartmann wound dressings are available through HARTMANN and Independence Australia only. If you would like to order Hartmann Wound Care products, please call HARTMANN customer service on 1800 805 839 or Independence Australia on 1300 788 855.

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</thead>
<tbody>
<tr>
<td>4944F</td>
<td>dressing non adherent 7.5 cm x 10 cm dressing, 10</td>
<td>‡1</td>
<td>..</td>
<td>15.58</td>
<td>6.00</td>
<td>Atrauman 499513 HR</td>
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</table>

DRESSING TULLE NON GAUZE PARAFFIN
<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
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<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>4909J</td>
<td>dressing tulle non gauze paraffin 7.6 cm x 7.6 cm dressing, 1</td>
<td>10</td>
<td>1</td>
<td>..</td>
<td>*16.06</td>
<td>6.00</td>
<td>Adaptic 2012 JJ</td>
</tr>
<tr>
<td>4646M</td>
<td>dressing with silver 10 cm x 10 cm dressing: hydroactive, 5 dressings</td>
<td>‡1</td>
<td>..</td>
<td>..</td>
<td>176.22</td>
<td>6.00</td>
<td>Biatain Ag 9622 CT</td>
</tr>
<tr>
<td>4647N</td>
<td>dressing with silver 12.5 cm x 12.5 cm dressing: hydroactive, 5 dressings</td>
<td>‡1</td>
<td>..</td>
<td>..</td>
<td>191.63</td>
<td>6.00</td>
<td>Biatain Ag 9632 CT</td>
</tr>
</tbody>
</table>

**DRESSING WITH SILVER**

**Authority required**

For wounds where there is evidence of critical colonisation and for well-assessed chronic wounds that have not responded to conventional dressings.

**Note**

Coloplast dressings are available via a range of distributors. However, Coloplast's principal agreement to ensure correct RPBS Price to Pharmacy and ready supply has been secured with Independence Australia on 1300 788 855 and BrightSky on 1300 290 400. Please note that Coloplast is unable to guarantee ready supply or rebate for price differences on purchases outside these distributors.

<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Restriction, Manner of Administration and Form</th>
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</tr>
</thead>
<tbody>
<tr>
<td>4648P</td>
<td>dressing with silver 10 cm x 10 cm dressing: tulle, 3 dressings</td>
<td>‡1</td>
<td>..</td>
<td>..</td>
<td>44.12</td>
<td>6.00</td>
<td>Atrauman Ag 499572 HR</td>
</tr>
</tbody>
</table>

**GAUZE AND COTTON TISSUE COMBINE ROLL**

**Authority required**

For wounds where there is evidence of critical colonisation and for well-assessed chronic wounds that have not responded to conventional dressings.

**Note**

Hartmann wound dressings are available through HARTMANN and Independence Australia only. If you would like to order Hartmann Wound Care products, please call HARTMANN customer service on 1800 805 839 or Independence Australia on 1300 788 855.

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</tr>
</thead>
<tbody>
<tr>
<td>4761N</td>
<td>gauze and cotton tissue combine roll 10 cm x 10 m roll: wrapped pack, 1 pack</td>
<td>‡1</td>
<td>..</td>
<td>..</td>
<td>17.55</td>
<td>6.00</td>
<td>JJ 12010 JJ</td>
</tr>
</tbody>
</table>

**GAUZE AND COTTON TISSUE COMBINE ROLL**

**Note**

Smith & Nephew products are distributed via the three major wholesalers, API, Sigma and Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS agreed pricing from distributors other than those aforementioned.

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</tr>
</thead>
<tbody>
<tr>
<td>4767X</td>
<td>gauze and cotton tissue combine roll 9 cm x 10 m roll: wrapped pack, 1 pack</td>
<td>‡1</td>
<td>..</td>
<td>..</td>
<td>11.72</td>
<td>6.00</td>
<td>BSN 2902165 BV</td>
</tr>
</tbody>
</table>

**TAPE NON WOVEN RETENTION POLYACRYLATE**

**Note**

Molnlycke Healthcare products are distributed through leading pharmacy distributors. To best ensure product availability at RPBS agreed prices, special arrangements have been made with API and Independence Australia Health Solutions (IAHS). IAHS orders can be placed on: Tel: 1300 788 855; or Email customerservice@independenceaustralia.com. Molnlycke Healthcare are not able to ensure product availability or pricing on listed products beyond these two suppliers.

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<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>4917T</td>
<td>tape non woven retention polyacrylate 2.5 cm x 10 m tape, 1 roll</td>
<td>‡1</td>
<td>..</td>
<td>..</td>
<td>11.38</td>
<td>6.00</td>
<td>Mefix 310250 MH</td>
</tr>
</tbody>
</table>

**TAPE NON WOVEN RETENTION POLYACRYLATE**

**Note**

Smith & Nephew products are distributed via the three major wholesalers, API, Sigma and Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS agreed pricing from distributors other than those aforementioned.

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</tr>
</thead>
<tbody>
<tr>
<td>4915Q</td>
<td>tape non woven retention polyacrylate 2.5 cm x 9.1 m tape, 1 roll</td>
<td>‡1</td>
<td>..</td>
<td>..</td>
<td>13.21</td>
<td>6.00</td>
<td>Medipore 2961 MM</td>
</tr>
</tbody>
</table>

**TAPE PLASTER ADHESIVE ELASTIC**

**Note**

Smith & Nephew products are distributed via the three major wholesalers, API, Sigma and Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS agreed pricing from distributors other than those aforementioned.

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</tr>
</thead>
<tbody>
<tr>
<td>4780N</td>
<td>tape plaster adhesive elastic 2.5 cm x 2.5 m tape, 1 roll</td>
<td>‡1</td>
<td>..</td>
<td>..</td>
<td>13.64</td>
<td>6.00</td>
<td>Leukoplast 01071-00 BV</td>
</tr>
<tr>
<td>4781P</td>
<td>tape plaster adhesive elastic 5 cm x 2.5 m tape, 1 roll</td>
<td>‡1</td>
<td>..</td>
<td>..</td>
<td>19.92</td>
<td>6.00</td>
<td>Leukoplast 01072-00 BV</td>
</tr>
<tr>
<td>4782Q</td>
<td>tape plaster adhesive elastic 7.5 cm x 2.5 m tape, 1 roll</td>
<td>‡1</td>
<td>..</td>
<td>..</td>
<td>23.80</td>
<td>6.00</td>
<td>Leukoplast 01073-00 BV</td>
</tr>
</tbody>
</table>

**TAPE PLASTER ADHESIVE HYPOALLERGENIC**

**Note**

Smith & Nephew products are distributed via the three major wholesalers, API, Sigma and Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS agreed pricing from distributors other than those aforementioned.
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</tr>
</thead>
<tbody>
<tr>
<td>4783R</td>
<td>tape plaster adhesive hypoallergenic 1.25 cm x 5 m tape, 1 roll</td>
<td>‡1</td>
<td>..</td>
<td>..</td>
<td>10.92</td>
<td>6.00</td>
<td>Leukopor 2471 BV</td>
</tr>
<tr>
<td>4785W</td>
<td>tape plaster adhesive hypoallergenic 1.25 cm x 5 m tape, 1 roll</td>
<td>‡1</td>
<td>..</td>
<td>..</td>
<td>11.22</td>
<td>6.00</td>
<td>Leukosilk 1021 BV</td>
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<tr>
<td>4787Y</td>
<td>tape plaster adhesive hypoallergenic 2.5 cm x 5 m tape, 1 roll</td>
<td>‡1</td>
<td>..</td>
<td>..</td>
<td>14.02</td>
<td>6.00</td>
<td>Leukosilk 1022 BV</td>
</tr>
<tr>
<td>4794H</td>
<td>tape plaster adhesive hypoallergenic 2.5 cm x 5 m tape, 1 roll</td>
<td>‡1</td>
<td>..</td>
<td>..</td>
<td>13.46</td>
<td>6.00</td>
<td>Leukopor 2472 BV</td>
</tr>
<tr>
<td>4788B</td>
<td>tape plaster adhesive hypoallergenic 5 cm x 5 m stretch tape, 1 roll</td>
<td>‡1</td>
<td>..</td>
<td>..</td>
<td>17.55</td>
<td>6.00</td>
<td>Leukoflex 1124 BV</td>
</tr>
<tr>
<td>4789C</td>
<td>tape plaster adhesive hypoallergenic 5 cm x 5 m stretch tape, 1 roll</td>
<td>‡1</td>
<td>..</td>
<td>..</td>
<td>18.05</td>
<td>6.00</td>
<td>Leukosilk 1024 BV</td>
</tr>
<tr>
<td>4790D</td>
<td>tape plaster adhesive hypoallergenic 5 cm x 5 m stretch tape, 1 roll</td>
<td>‡1</td>
<td>..</td>
<td>..</td>
<td>17.17</td>
<td>6.00</td>
<td>Leukopor 2474 BV</td>
</tr>
<tr>
<td>4848E</td>
<td>tape plaster adhesive hypoallergenic 1.9 cm x 5.4 m dispenser tape, 1 roll</td>
<td>‡1</td>
<td>..</td>
<td>..</td>
<td>11.39</td>
<td>6.00</td>
<td>Nexcare Durable Cloth First Aid Tape 799 MM</td>
</tr>
<tr>
<td>4849F</td>
<td>tape plaster adhesive hypoallergenic 1.9 cm x 7.3 m dispenser tape, 1 roll</td>
<td>‡1</td>
<td>..</td>
<td>..</td>
<td>11.39</td>
<td>6.00</td>
<td>Nexcare Gentle Paper First Aid Tape 789 MM</td>
</tr>
</tbody>
</table>

**TAPE PLASTER ADHESIVE HYPOALLERGENIC**

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</thead>
<tbody>
<tr>
<td>4239D</td>
<td>tape plaster adhesive with silicone 2 cm x 3 m tape, 1 roll</td>
<td>‡1</td>
<td>..</td>
<td>..</td>
<td>21.71</td>
<td>6.00</td>
<td>Mepitac 298300 MH</td>
</tr>
<tr>
<td>4240E</td>
<td>tape plaster adhesive with silicone 4 cm x 1.5 m tape, 1 roll</td>
<td>‡1</td>
<td>..</td>
<td>..</td>
<td>21.71</td>
<td>6.00</td>
<td>Mepitac 298400 MH</td>
</tr>
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</table>
Section 2

Standard Packs and Prices

NOTE—

Standard packs and prices (including mark-up, but without dispensing fee and dangerous drug fee) are for items against the price of which an asterisk (*) is shown in Section 1 of the Schedule.
<table>
<thead>
<tr>
<th>Code</th>
<th>Name, Form/Strength</th>
<th>Pack and Price</th>
<th>Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>10031Y</td>
<td>alprostadil 10 microgram injection [1 x 10 microgram vial] (&amp;) inert substance diluent [1 syringe], 1 pack</td>
<td>1@ 16.51</td>
<td>PF</td>
</tr>
<tr>
<td>10030X</td>
<td>alprostadil 20 microgram injection [1 x 20 microgram vial] (&amp;) inert substance diluent [1 syringe], 1 pack</td>
<td>1@ 21.07</td>
<td>PF</td>
</tr>
<tr>
<td>4118R</td>
<td>ALUMINIUM HYDROXIDE with MAGNESIUM HYDROXIDE and SIMETHIONE Orally suspensio300 mg; 400 mg; 30 mg per 5 mL, 500 mL, 1 ph</td>
<td>1@ 8.11</td>
<td>JT</td>
</tr>
<tr>
<td>4453J</td>
<td>ALUMINIUM HYDROXIDE with MAGNESIUM HYDROXIDE and SIMETHIONE Tablets 400 mg; 400 mg; 40 mg, 100 pack</td>
<td>100@ 19.85</td>
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Amira 300 (AF)

AMISULPRIDE

Amisulpride 100 Winthrop (WA)

Amisulpride 200 Winthrop (WA)

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Amisulpride Sandoz (SZ)

AMITRIPTYLINE

Amlo 10 (QA)

Amlo 5 (QA)

AMLODIPINE

AMLODIPINE + ATORVASTATIN

AMLODIPINE + VALSARTAN

AMLODIPINE + VALSARTAN + HYDROCHLOROTHIAZIDE

AMMONIUM + SENEGA ROOT

AMOROLFINE

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<td>ZolaCos CP 3.6/50 (AP)</td>
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<tr>
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<td>Zoladex Implant (AP)</td>
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<td>Zytiga (JC)</td>
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**ZONISAMIDE**

**ZOPICLONE**

**Zopiclone**

**Zopral Schedule**

**Zopral OD (AF)**

**Zovirax (GK)**

**Zovirax 200 mg (GK)**

**Zuclopenthixol Decanoate**

**Zumenon (AB)**

**Zumenon (AB)**

**Zumenon (AB)**

**Zyban (AS)**

**Zydol (QA)**

**Zydol SR 100 (QA)**

**Zydol SR 200 (QA)**

**Zypine (AF)**

**Zypine ODT (AF)**

**Zyprena (LY)**

**Zypresa (LY)**

**Zyrtec (JT)**

**Zytiga (JC)**

**Antineoplastic and Immunomodulating Agents**
THERAPEUTIC GROUP PREMIUM POLICY

PHARMACEUTICAL BENEFIT ITEMS WHICH HAVE A THERAPEUTIC GROUP PREMIUM WITH EFFECT FROM 1 September 2014

The Schedule of Pharmaceutical Benefits shows differences in price in some therapeutic groups where alternative drugs may have a therapeutic group premium.

The Therapeutic Group Premium Policy applies within narrowly defined therapeutic sub-groups where the drugs concerned are of similar safety and health outcomes.

The Australian Government, through the PBS, subsidises up to the price of the lowest priced drug in the group. This means that consumers may have to pay for more expensive drugs (those with a therapeutic group premium). This extra amount does not count towards their PBS safety net threshold.

Therapeutic group premiums apply where a prescriber has prescribed a drug within a therapeutic group that attracts a therapeutic group premium and has not sought an exemption from Department of Human Services on clinical grounds.

The exemption provisions are:

- adverse effects occurring with all of the base-priced drugs; or
- drug interactions occurring with all of the base-priced drugs; or
- drug interactions expected to occur with all of the base-priced drugs; or
- transfer to a base-priced drug would cause patient confusion resulting in problems with compliance.

The premiums are not a Government charge but reflect the fact that the supplier(s) of the drug charge a price higher than the Government is willing to subsidise.

Under the Therapeutic Group Premium Policy drug substitution by pharmacists is not permitted.

For ease of prescribing and dispensing, and in the interests of your patients, the following list shows those PBS drugs that attract a therapeutic group premium.
<table>
<thead>
<tr>
<th>Premium Priced Brand</th>
<th>Form and Strength</th>
<th>Therapeutic Group Premium</th>
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<td>ANGIOTENSIN II ANTAGONISTS</td>
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<td></td>
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<tr>
<td>Teveten</td>
<td>eprosartan 400 mg tablet, 28</td>
<td>3.50</td>
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<tr>
<td>Teveten</td>
<td>eprosartan 600 mg tablet, 28</td>
<td>3.50</td>
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<tr>
<td>Olmetec</td>
<td>olmesartan medoxomil 20 mg tablet, 30</td>
<td>2.51</td>
</tr>
<tr>
<td>Olmetec</td>
<td>olmesartan medoxomil 40 mg tablet, 30</td>
<td>2.51</td>
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</tbody>
</table>

The base-priced drugs in this therapeutic group are candesartan cilexetil, irbesartan, losartan and valsartan.
The Schedule of Pharmaceutical Benefits shows differences in price between some alternative brands of the same drug product. Manufacturers can develop generic equivalents and apply to have them listed on the PBS. In doing this, manufacturers need to ensure that they comply with the relevant legislation applicable to patents. These brands are clinically equivalent and must undergo the same strict quality controls. Although these brands are designed to act on the body in exactly the same way, they are usually cheaper than the originator brands.

The Australian Government, through the PBS, subsidises up to the price of the lowest priced brand (except in those instances where the lowest priced brand has, as part of its price, a therapeutic group premium). This means that consumers may have to pay extra for more expensive brands (those with a brand premium). This extra amount does not count towards their PBS safety net threshold.

Brand substitution by pharmacists without reference to the prescriber is permitted for PBS prescriptions where:

- the patient agrees to the substitution;
- the brands are identified in the Schedule of Pharmaceutical Benefits as being interchangeable;
- the prescriber has not indicated on the prescription form that substitution is not to occur; and
- substitution is permitted under the relevant State or Territory legislation.

Prescription forms supplied by Department of Human Services contain a box to be ticked where brand substitution is not to take place. Prescribers not using these prescription forms should endorse the prescription if brand substitution is not permitted. Where a stamp is used for this purpose, the prescriber will be required to initial the stamped statement.

For ease of prescribing and dispensing, and in the interests of your patients, the following list shows those PBS drugs that attract a brand premium and that can be substituted where permitted. They are listed alphabetically, by brand name, with the brand premium and benchmark brand(s) cited in the last column.
<table>
<thead>
<tr>
<th>Premium Priced Brand</th>
<th>Form and Strength</th>
<th>Max. Qty</th>
<th>Brand Premium $</th>
<th>Benchmark Priced Brands</th>
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<tr>
<td>Abrocillin-V</td>
<td>phenoxyacetamide/penicillin 150 mg/5 mL oral liquid, 100 mL</td>
<td>2</td>
<td>1.90</td>
<td>Cilicaine V</td>
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<td>Accupril</td>
<td>quinapril 10 mg tablet, 30</td>
<td>30</td>
<td>1.47</td>
<td>Acquin Aspen 10; APO-Quinapril; Aquinafil; Qpril 10</td>
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<tr>
<td></td>
<td>quinapril 20 mg tablet, 30</td>
<td>30</td>
<td>1.46</td>
<td>Acquin Aspen 20; APO-Quinapril; Aquinafil; Qpril 20; Quinapril-RA; Quinapril generic; quinapril generic health</td>
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<td>Actilax</td>
<td>LACTULOSE Mixture 3.34 g per 5 mL, 500 mL, 1</td>
<td>1</td>
<td>0.89</td>
<td>Genlac; GenRx Lactulose</td>
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<td>LACTULOSE Mixture 3.34 g per 5 mL, 500 mL, 1</td>
<td>3</td>
<td>2.67</td>
<td>Genlac; GenRx Lactulose</td>
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<td>Adalat</td>
<td>nifdefine 10 mg tablet, 60</td>
<td>60</td>
<td>0.84</td>
<td>Adefin 10</td>
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<tr>
<td>Adalat 20</td>
<td>nifdefine 20 mg tablet, 60</td>
<td>60</td>
<td>1.57</td>
<td>Adefin 20; GenRx Nifdefine; Nifedipine</td>
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<tr>
<td>Adalat Oros 30</td>
<td>nifdefine 30 mg tablet: modified release, 30 tablets</td>
<td>30</td>
<td>1.82</td>
<td>Addos XR 30; Adefin XL 30; APO-Nifedipine XR</td>
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<tr>
<td>Adalat Oros 60</td>
<td>nifdefine 60 mg tablet: modified release, 30 tablets</td>
<td>30</td>
<td>1.99</td>
<td>Addos XR 60; Adefin XL 60; APO-Nifedipine XR</td>
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<td>Aldactone</td>
<td>spironolactone 100 mg tablet, 100</td>
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<td>3.16</td>
<td>Spiractin 100</td>
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<td>spironolactone 25 mg tablet, 100</td>
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<td>2.59</td>
<td>Spiractin 25</td>
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<td>methylprednisolone 25 mg tablet, 100</td>
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<td>3.54</td>
<td>Hydrocortisone 250</td>
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<td>Alphagan</td>
<td>bromonidine tartrate 0.2% eye drops, 5 mL</td>
<td>1</td>
<td>1.63</td>
<td>Enidin</td>
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<td>Amaryl</td>
<td>glimepiride 1 mg tablet, 30</td>
<td>30</td>
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<td>APO-Glimepiride; Aylide 1; Diurex 1; Ribonid 1; Glimipride GA; Glimipride Sandoz</td>
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<td>glimepiride 2 mg tablet, 30</td>
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<td>2.80</td>
<td>APO-Glimepiride; Aylide 2; Diurex 2; Ribonid 2; Glimipride GA; Glimipride Sandoz</td>
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<td>glimepiride 3 mg tablet, 30</td>
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<td>glimepiride 4 mg tablet, 30</td>
<td>30</td>
<td>2.81</td>
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<td>Amoxil</td>
<td>amoxicillin 125 mg/5 mL oral liquid: powder for, 100 mL</td>
<td>1</td>
<td>3.35</td>
<td>Alphamox 125; Amoxicillin Sandoz; APO-Amoxicillin; Bgramin; Chem mart Amoxicillin; GenRx Amoxicillin; Ranmox; Terry White Chemists Amoxicillin</td>
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<td>amoxicillin 250 mg capsule, 20</td>
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<td>3.37</td>
<td>Alphamox 250; Amoxicillin AN; Amoxicillin-RA; Amoxicillin Ranbaxy; Amoxicillin Sandoz; APO-Amoxicillin; Chem mart Amoxicillin; Cilax; Terry White Chemists Amoxicillin</td>
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<td>amoxicillin 500 mg capsule, 20</td>
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<td>Alphamox 500; Amoxicillin AN; Amoxicillin-RA; Amoxicillin generic; 500; Amoxicillin Ranbaxy; Amoxicillin Sandoz; APO-Amoxicillin; Chem mart Amoxicillin; Cilax; Terry White Chemists Amoxicillin</td>
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<tr>
<td>Amoxil Forte</td>
<td>amoxicillin 250 mg/5 mL oral liquid: powder for, 100 mL</td>
<td>1</td>
<td>3.41</td>
<td>Alphamox 250; Amoxicillin Sandoz; APO-Amoxicillin; Bgramin; Chem mart Amoxicillin; Cilax; GenRx Amoxicillin; Ranmox; Terry White Chemists Amoxicillin</td>
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<td>Anafranil 25</td>
<td>clomipramine hydrochloride 25 mg tablet, 50</td>
<td>50</td>
<td>2.74</td>
<td>Chem mart Clomipramine; GenRx Clomipramine; Placidil; Terry White Chemists Clomipramine</td>
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<tr>
<td>Anaprox 550</td>
<td>naproxen sodium 550 mg tablet, 50</td>
<td>50</td>
<td>2.17</td>
<td>Crysanal</td>
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<tr>
<td>Androcur</td>
<td>cyproterone acetate 50 mg tablet, 20</td>
<td>20</td>
<td>2.44</td>
<td>Cyprocur 50; Cyroprone; Cyporone AN; Cyproterone Sandoz; GenRx Cyproterone Acetate; Procur</td>
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<td>cyproterone acetate 50 mg tablet, 50</td>
<td>100</td>
<td>2.24</td>
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<td>Androcur-100</td>
<td>cyproterone acetate 100 mg tablet, 50</td>
<td>50</td>
<td>0.94</td>
<td>Cyprocur 100; Cyroprone-100; Cyproterone AN; Cyproterone Sandoz; GenRx Cyproterone Acetate; Procur 100</td>
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<tr>
<td>Anginine Stabilised</td>
<td>glycyl trinitrate 600 microgram tablet: sublingual, 100 tablets</td>
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<td>2.94</td>
<td>Lycinate</td>
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<tr>
<td>Aristocort 0.02%</td>
<td>triamcinolone acetonide 0.02% (200 microgram/g) cream, 100 g</td>
<td>2</td>
<td>3.78</td>
<td>Tricortone</td>
</tr>
<tr>
<td></td>
<td>triamcinolone acetonide 0.02% (200 microgram/g) ointment, 100 g</td>
<td>2</td>
<td>3.78</td>
<td>Tricortone</td>
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<tr>
<td>Aropax</td>
<td>paroxetine 20 mg tablet, 30</td>
<td>30</td>
<td>2.90</td>
<td>Chem mart Paroxetine; Extine 20; GenRx Paroxetine; Paroxetine AN; Paroxetine-RA; Paroxetine Sandoz; Paxtine; Roxet 20; Terry White Chemists Paroxetine</td>
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<tr>
<td>Atrix</td>
<td>aspirin 100 mg tablet, 112</td>
<td>112</td>
<td>2.32</td>
<td>Adesan; APO-Candesartan; Auro-Candesartan 16; Candesartan AN; Candesartan Aspen 16; Candesartan-RA; Candesartan GH; Candesartan RBX; Candesartan Sandoz; Chem mart Candesartan; Pharmacol Candesartan 16; Terry White Chemists Candesartan</td>
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<td>Atacand</td>
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<td>30</td>
<td>2.01</td>
<td>Adesan; APO-Candesartan; Auro-Candesartan 32; Candesartan AN; Candesartan Aspen 32; Candesartan-RA; Candesartan GH; Candesartan RBX; Candesartan Sandoz; Chem mart Candesartan; Pharmacol Candesartan 32; Terry White Chemists Candesartan</td>
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<td>Adesan; APO-Candesartan; Auro-Candesartan 4; Candesartan AN; Candesartan Aspen 4; Candesartan-RA; Candesartan GH; Candesartan RBX; Candesartan Sandoz; Chem mart Candesartan</td>
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<tr>
<td>Premium Priced Brand</td>
<td>Form and Strength</td>
<td>Max. Qty</td>
<td>Brand Premium $</td>
<td>Benchmark Priced Brands</td>
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<tr>
<td>----------------------</td>
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<tr>
<td><strong>Betaloc</strong></td>
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<tr>
<td><strong>Azopt</strong></td>
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</tr>
<tr>
<td><strong>Avanza SolTab</strong></td>
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<tr>
<td><strong>Avanza</strong></td>
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<tr>
<td><strong>Aurorix 300 mg</strong></td>
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<tr>
<td><strong>Atrovent Adult</strong></td>
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<tr>
<td><strong>Atrovent</strong></td>
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<tr>
<td><strong>Augmentin Duo forte</strong></td>
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<tr>
<td><strong>Augmentin Duo 400</strong></td>
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<td><strong>Augmentin</strong></td>
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<td><strong>Aurorix</strong></td>
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<td></td>
<td></td>
</tr>
<tr>
<td><strong>Avanza SoTab</strong></td>
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<tr>
<td><strong>Azopt</strong></td>
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</tr>
<tr>
<td><strong>Betaloc</strong></td>
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</table>

**Premium Priced Brand**

- **Betaloc**
- **Azopt**
- **Avanza SolTab**
- **Avanza**
- **Aurorix 300 mg**
- **Atrovent Adult**
- **Atrovent**
- **Augmentin Duo forte**
- **Augmentin Duo 400**
- **Augmentin**
- **Aurorix**
- **Avanza SoTab**
- **Azopt**
- **Betaloc**

**Brand Premium**

- **Betaloc**
- **Azopt**
- **Avanza SolTab**
- **Avanza**
- **Aurorix 300 mg**
- **Atrovent Adult**
- **Atrovent**
- **Augmentin Duo forte**
- **Augmentin Duo 400**
- **Augmentin**
- **Aurorix**
- **Avanza SoTab**
- **Azopt**
- **Betaloc**

**Max. Qty**

- **Betaloc**
- **Azopt**
- **Avanza SolTab**
- **Avanza**
- **Aurorix 300 mg**
- **Atrovent Adult**
- **Atrovent**
- **Augmentin Duo forte**
- **Augmentin Duo 400**
- **Augmentin**
- **Aurorix**
- **Avanza SoTab**
- **Azopt**
- **Betaloc**

**Brand Premium $**

- **Betaloc**
- **Azopt**
- **Avanza SolTab**
- **Avanza**
- **Aurorix 300 mg**
- **Atrovent Adult**
- **Atrovent**
- **Augmentin Duo forte**
- **Augmentin Duo 400**
- **Augmentin**
- **Aurorix**
- **Avanza SoTab**
- **Azopt**
- **Betaloc**

**Benchmark Priced Brands**

- **Betaloc**
- **Azopt**
- **Avanza SolTab**
- **Avanza**
- **Aurorix 300 mg**
- **Atrovent Adult**
- **Atrovent**
- **Augmentin Duo forte**
- **Augmentin Duo 400**
- **Augmentin**
- **Aurorix**
- **Avanza SoTab**
- **Azopt**
- **Betaloc**

**Chem mart Metoprolol; GenRx Metoprolol; Metoprolol Sandoz;**

**Milivin OD 45; Mirtazapine AN ODT; Mirtazapine Sandoz ODT 45;**

**Amira 300; Chem mast Moclobemide; Clobexin; GenRx Moclobemide; Moclobemide AN; Moclobemide Sandoz; Moheval; Terry White Chemists Moclobemide;**

**APO-Mirtazapine; Aurozapine 30; Axit 30; Chem mast Mirtazapine; GenRx Mirtazapine; Mirtazapine AN; Mirtazapine-DP; Mirtazapine-GA; Mirtazapine GH; Mirtazapine Sandoz; Mirtazon; Terry White Chemists Mirtazapine;**

**APO-Mirtazapine; Aurozapine 45; Axit 45; Chem mast Mirtazapine; Mirtazapine AN; Mirtazapine Sandoz;**

**Millivin OD 15; Mirtazapine AN ODT; Mirtazapine Sandoz ODT 15; Remeron SoTab;**

**Milivin OD 30; Mirtazapine AN ODT; Mirtazapine Sandoz ODT 30; Remeron SoTab;**

**Milivin OD 45; Mirtazapine AN ODT; Mirtazapine Sandoz ODT 45; Remeron SoTab;**

**BrinzQuin; Chem mast Metoprolol; GenRx Metoprolol; Metoprolol Sandoz; Metrol 100; Minax 100; Terry White Chemists Metoprolol;**

**Chem mast Metoprolol; GenRx Metoprolol; Metoprolol Sandoz; Metrol 50; Minax 50; Terry White Chemists Metoprolol;**
<table>
<thead>
<tr>
<th>Premium Priced Brand</th>
<th>Form and Strength</th>
<th>Max. Qty</th>
<th>Brand Premium $</th>
<th>Benchmark Priced Brands</th>
</tr>
</thead>
<tbody>
<tr>
<td>Betnovate 1/2</td>
<td>betamethasone (as valerate) 0.05% (500 microgram/g) cream, 15 g</td>
<td>1</td>
<td>2.94</td>
<td>Cortival 1/2</td>
</tr>
<tr>
<td>Betnovate 1/5</td>
<td>betamethasone (as valerate) 0.02% (200 microgram/g) cream, 100 g</td>
<td>2</td>
<td>6.88</td>
<td>Cortival 1/5</td>
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<tr>
<td>Betoptic</td>
<td>beta blocker 0.5% eye drops, 5 mL</td>
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<td>2.08</td>
<td>BetoQuin</td>
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<tr>
<td>Brexinor</td>
<td>ethinylestradiol 35 microgram + norethisterone 500 microgram tablet [84] (1) inert substance tablet [28], 112 [x 28]</td>
<td>4</td>
<td>7.67</td>
<td>Norimin 28 Day</td>
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<tr>
<td>Brexinor-1</td>
<td>ethinylestradiol 35 microgram + norethisterone 1 mg tablet [84] (1) inert substance tablet [28], 112 [x 28]</td>
<td>4</td>
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<td>Norimin-1 28 Day</td>
</tr>
<tr>
<td>Capoten</td>
<td>captopril 25 mg tablet, 90</td>
<td>90</td>
<td>5.20</td>
<td>APO-Captopril; Captopril Sandoz; GenRx Captopril; Zedace</td>
</tr>
<tr>
<td>Carafate</td>
<td>sucralfate 1 g tablet, 120</td>
<td>120</td>
<td>2.30</td>
<td>Ulcyte</td>
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<tr>
<td>Cefaclor</td>
<td>cefaclor 125 mg/5 mL oral liquid: powder for, 100 mL</td>
<td>1</td>
<td>5.86</td>
<td>Aclo 125; APO-Cefaclor; Chem mart Cefaclor; GenRx Cefaclor; Keflor; Terry White Chemists Cefaclor</td>
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<tr>
<td>Cefaclor 250</td>
<td>cefaclor 250 mg/5 mL oral liquid: powder for, 75 mL</td>
<td>1</td>
<td>6.10</td>
<td>Aclo 250; APO-Cefaclor; Chem mart Cefaclor; GenRx Cefaclor; Keflor; Terry White Chemists Cefaclor</td>
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<td>Celestone-M</td>
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<td>2.46</td>
<td>Antroquoril</td>
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<td>Cellufresh</td>
<td>carmellose sodium 0.5% (2 mg/0.4 mL) eye drops, 30 x 0.4 mL unit doses</td>
<td>3</td>
<td>4.77</td>
<td>Optifresh Tears</td>
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<tr>
<td>Celluvisc</td>
<td>carmellose sodium 1% (4 mg/0.4 mL) eye drops, 30 x 0.4 mL unit doses</td>
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<td>4.77</td>
<td>Optifresh Plus</td>
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<td>Ciloxan</td>
<td>ciprofloxacin 0.3% eye drops, 5 mL</td>
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<td>2.06</td>
<td>Ciloxin</td>
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<td>Cipramil</td>
<td>ciprofloxacin 20 mg tablet, 28</td>
<td>28</td>
<td>4.45</td>
<td>APO-Ciprofloxitin; Auro-Ciprofloxitin 20; Celapram; Celica; Chem mart Ciprofloxitin; Citalopram; Citalopram Generichealth; Citalopram Sandoz; Pharmacor Citalo 20; Talam; Terry White Chemists Ciprofloxitin</td>
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<td>Ciproxin 250</td>
<td>ciprofloxacin 250 mg tablet, 14</td>
<td>14</td>
<td>0.46</td>
<td>C-Flox 250; Ciprofloxitin-DRLA; Ciprofloxitin Sandoz; Ciprofloxitin; GenRx Ciprofloxitin</td>
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<tr>
<td>Ciproxin 500</td>
<td>ciprofloxacin 500 mg tablet, 14</td>
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<td>0.48</td>
<td>C-Flox 500; Cifran; Ciprofloxitin 500; Ciprofloxitin AN; Ciprofloxitin-BW; Ciprofloxitin-DRLA; Ciprofloxitin-GA; Ciprofloxitin Sandoz; Ciprofloxitin 500; GenRx Ciprofloxitin; Lopix 500</td>
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<td>Ciproxin 750</td>
<td>ciprofloxacin 750 mg tablet, 14</td>
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<td>0.47</td>
<td>C-Flox 750; Cifran; Ciprofloxitin 750; Ciprofloxitin AN; Ciprofloxitin-BW; Ciprofloxitin-DRLA; Ciprofloxitin-GA; Ciprofloxitin Sandoz; Ciprofloxitin 750; GenRx Ciprofloxitin; Lopix 750</td>
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<td>Colgout</td>
<td>colchina 500 microgram tablet, 30</td>
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<td>Lengout</td>
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<td>Coversyl 2.5mg</td>
<td>perindopril arginine 2.5 mg tablet, 30</td>
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<td>PREXUM 2.5</td>
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<td>clindamycin 150 mg capsule, 24</td>
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<td>2.03</td>
<td>Cleocin</td>
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<td>Daonil</td>
<td>glibenclamide 5 mg tablet, 100</td>
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<td>1.44</td>
<td>Gilmel</td>
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<td>methylprednisolone acetate 40 mg/mL injection, 5 x 1 mL vials</td>
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<td>Depo-Nisolone</td>
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<tr>
<td>Depo-Provera</td>
<td>medroxyprogesterone acetate 150 mg/mL injection, 1 x 1 mL vial</td>
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<td>3.50</td>
<td>Depo-Ralovera</td>
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<td>1.85</td>
<td>APO-Metformin 500; Chem mart Metformin; Diaformin; Formet Aspen 500; GenRx Metformin; Glucobete 500; Metformin 500; Metformin AN; Metformin-GA; Metformin generichealth; Metformin Ranbaxy; Metformin Sandoz; Terry White Chemists Metformin</td>
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<td>Diabex 1000</td>
<td>metformin hydrochloride 1 g tablet, 90</td>
<td>90</td>
<td>1.85</td>
<td>APO-Metformin 1000; Chem mart Metformin 1000; Diaformin 1000; Formet 1000; GenRx Metformin; Glucobete 1000; Metformin AN; Metformin-GA; Metformin generichealth 1000; Metformin Ranbaxy 1000; Metformin Sandoz; Pharmacor Metformin 1000; Terry White Chemists Metformin 1000</td>
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<td>metformin hydrochloride 850 mg tablet, 60</td>
<td>60</td>
<td>1.85</td>
<td>APO-Metformin 850; Chem mart Metformin; Diaformin 850; Formet Aspen 850; GenRx Metformin; Glucobete 850; Glucophage; Metformin 850; Metformin AN; Metformin-GA; Metformin generichealth; Metformin Ranbaxy; Metformin Sandoz; Terry White Chemists Metformin</td>
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<td>Diabex XR</td>
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<td>1.85</td>
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<td>Diprosone</td>
<td>betamethasone (as dipropionate) 0.05% cream, 15 g</td>
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<td>2.45</td>
<td>Eleuphrat</td>
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<td>Diprosone</td>
<td>betamethasone (as dipropionate) 0.05% ointment, 15 g</td>
<td>1</td>
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<td>Eleuphrat</td>
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<tr>
<td>Brand Premium</td>
<td>Brand Premium $</td>
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<tr>
<td>Doryx</td>
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<td>Dulcolax</td>
<td>bisacodyl 10 mg suppository, 10</td>
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<td>Petrus Bisacodyl Suppositories</td>
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<td>paraffin 1 g/1 g eye ointment, 3.5 g</td>
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<td>2.54</td>
<td>Poly Vis</td>
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<td>E.E.S. 200</td>
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<td>E-Mycin</td>
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<td>E-Mycin 400</td>
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<td>Elocon</td>
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<td>Epilim EC</td>
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<td>200</td>
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<td>Sodium Valproate Sandoz; Valprease 200; Valpro 200; Valproate Winthrop EC 200</td>
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<td>Eryc</td>
<td>erythromycin 250 mg capsule: enteric, 25</td>
<td>25</td>
<td>2.91</td>
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<td>Fasigyn</td>
<td>piroxicam 10 mg capsule, 4</td>
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<td>3.00</td>
<td>Simplotan</td>
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<td>piroxicam 20 mg capsule, 25</td>
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<td>2.86</td>
<td>Chem mart Piroxicam; GenRx Piroxicam; Mobilis 10; Terry White Chemists Piroxicam</td>
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<td>Mobilis D-20</td>
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<tr>
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<td>alendronate 70 mg + colecalciferol 140 microgram tablet, 4</td>
<td>4</td>
<td>2.49</td>
<td>Alendronate plus D3-DRLA; Dronalen Plus; Fosat Plus</td>
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<tr>
<td>Genteal gel</td>
<td>HYPROMELLOSE Eye drops 3 mg per mL (0.3%), 15 mL (contains sodium perborate as preservative), 1 syringe</td>
<td>1</td>
<td>1.95</td>
<td>In a Wink Moisturising</td>
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<tr>
<td>Glucophage</td>
<td>metformin hydrochloride 850 mg tablet, 60</td>
<td>60</td>
<td>0.64</td>
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<td>Gopten</td>
<td>trandolapril 1 mg capsule, 28</td>
<td>28</td>
<td>3.49</td>
<td>APO-Trandolapril; Dolapril 1; Tranalpa; Trandolapril-DP</td>
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<td>Imdur 120 mg</td>
<td>isosorbide mononitrate 120 mg tablet: modified release, 30 tablets</td>
<td>30</td>
<td>3.37</td>
<td>Monodur 120 mg</td>
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<tr>
<td>Imdur Durule</td>
<td>isosorbide mononitrate 60 mg tablet: modified release, 30 tablets</td>
<td>30</td>
<td>3.37</td>
<td>Chem mart Isosorbide Mononitrate; Duride; GenRx Isosorbide Mononitrate; Imtrate 60 mg; Isomoni; Isosorbide AN; Monodur 60 mg; Terry White Chemists Isosorbide Mononitrate</td>
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<td>SUMATRIPTAN Tablet 50 mg (as succinate), 2</td>
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<td>APO-Sumatriptan; Chem mart Sumatriptan; Sumagran Aspen 50; Sumatab; Sumatran; Sumatriptan Sandoz; Terry White Chemists Sumatriptan</td>
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| | cephalixin 250 mg capsule, 20 | 40 | 8.64 | APO-Cephalexin; Cefalexin Sandoz; Cephalex 250; Cephalexin AN; Cephalexin generichealth; Chem mart Cephalexin; Clilex; GenRx Cephalexin; Ialex; Ilibex 250; Rancef; Terry White
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<th>Max. Qty</th>
<th>Benchmark Priced Brands</th>
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