Schedule of Pharmaceutical Benefits

Effective 1 June 2015 – 30 June 2015

This Schedule is also available at www.pbs.gov.au
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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Fees, Patient Contributions and Safety Net Thresholds

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

<table>
<thead>
<tr>
<th>Category</th>
<th>Subcategory</th>
<th>Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dispensing Fees:</td>
<td>Ready-prepared</td>
<td>$6.76</td>
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<tr>
<td></td>
<td>Dangerous drug fee</td>
<td>$2.71</td>
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<td></td>
<td>Extemporaneously-prepared</td>
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<td></td>
<td>Allowable additional patient charge*</td>
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<tr>
<td>Additional Fees (for safety net prices):</td>
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<tr>
<td></td>
<td>Extemporaneously-prepared</td>
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<td>Patient Co-payments:</td>
<td>General</td>
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<td>Concessional</td>
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<tr>
<td>Safety Net Thresholds:</td>
<td>General</td>
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<td>Concessional</td>
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<tr>
<td>Safety Net Card Issue Fee:</td>
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<td>$9.47</td>
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* 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

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

General Pharmaceutical Benefits
Additions

Addition – Item

10258X AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT PHENYLALANINE, amino acid formula with vitamins and minerals without phenylalanine oral liquid: powder for, 30 x 36 g sachets (PKU Anamix Junior)

10260B AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT PHENYLALANINE AND TYROSINE, amino acid formula with vitamins and minerals without phenylalanine and tyrosine oral liquid: powder for, 30 x 36 g sachets (TYR Anamix Junior)

10261C DIPHTHERIA TOXOID + TETANUS TOXOID, diphtheria toxoid 2 Lf/0.5 mL + tetanus toxoid 2 Lf/0.5 mL injection, 10 x 0.5 mL vials (MassBiologics tetanus and diphtheria toxoids adsorbed)

Addition – Brand

1003T Aciclovir Sandoz, HX – ACICLOVIR, aciclovir 200 mg tablet, 25

1007B Aciclovir Sandoz, HX – ACICLOVIR, aciclovir 200 mg tablet, 90

1081X Atenolol RBX, RA – ATENOLOL, atenolol 50 mg tablet, 30

8382E Diasp SR, QA – DIPYRIDAMOLE + ASPIRIN, dipyridamole 200 mg + aspirin 25 mg capsule: modified release, 60 capsules

9155W Depreta 30, DO – DULOXETINE, duloxetine 30 mg capsule: enteric, 28

9156X Depreta 60, DO – DULOXETINE, duloxetine 60 mg capsule: enteric, 28

2414C Frusemide RBX, RA – FRUSEMIDE, frusemide 20 mg tablet, 100

2412Y Frusemide RBX, RA – FRUSEMIDE, frusemide 40 mg tablet, 100

1834M Gabapentin GH, GQ – GABAPENTIN, gabapentin 300 mg capsule, 100

1835N Gabapentin GH, GQ – GABAPENTIN, gabapentin 400 mg capsule, 100

1512N Hydroxychloroquine RBX, RA – HYDROXYCHLOROQUINE, hydroxychloroquine sulfate 200 mg tablet, 100

2848X Logem, AL – LAMOTRIGINE, lamotrigine 25 mg tablet, 56

2849Y Logem, AL – LAMOTRIGINE, lamotrigine 50 mg tablet, 56

2850B Logem, AL – LAMOTRIGINE, lamotrigine 100 mg tablet, 56

2851C Logem, AL – LAMOTRIGINE, lamotrigine 200 mg tablet, 56

9331D APO-Lansoprazole ODT, TX – LANSOPRAZOLE, lansoprazole 15 mg tablet: orally disintegrating, 28 tablets

9477T APO-Lansoprazole ODT, TX – LANSOPRAZOLE, lansoprazole 30 mg tablet: orally disintegrating, 28 tablets

9478W APO-Lansoprazole ODT, TX – LANSOPRAZOLE, lansoprazole 30 mg tablet: orally disintegrating, 28 tablets

5264C Solu-Medrol, PF – METHYLprednisolone, methylprednisolone Powder for injection 1 g (as sodium succinate), 1
<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tr>
<td>1207M</td>
<td>Metoclopramide RBX, RA – METOCLOPRAMIDE, metoclopramide hydrochloride 10 mg</td>
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<tr>
<td>5151D</td>
<td>Metoclopramide RBX, RA – METOCLOPRAMIDE, metoclopramide hydrochloride 10 mg</td>
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<td>1324Q</td>
<td>Metoprolol RBX, RA – METOPROLOL TARTRATE, METOPROLOL TARTRATE Tablet 50 mg</td>
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<td>1325R</td>
<td>Metoprolol RBX, RA – METOPROLOL TARTRATE, METOPROLOL TARTRATE Tablet 100 mg</td>
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<td>1594X</td>
<td>Ondansetron SZ, RX – ONDANSETRON, ondansetron 4 mg tablet, 10</td>
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<td>8224W</td>
<td>Ondansetron SZ, RX – ONDANSETRON, ondansetron 4 mg tablet, 4</td>
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<td>5470X</td>
<td>Ondansetron SZ ODT, RX – ONDANSETRON, ONDANSETRON Tablet (orally disintegrating) 4 mg, 4</td>
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<td>5472B</td>
<td>Ondansetron SZ ODT, RX – ONDANSETRON, ONDANSETRON Tablet (orally disintegrating) 4 mg, 10</td>
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<td>1595Y</td>
<td>Ondansetron SZ, RX – ONDANSETRON, ondansetron 8 mg tablet, 10</td>
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<td>8225X</td>
<td>Ondansetron SZ, RX – ONDANSETRON, ondansetron 8 mg tablet, 4</td>
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<td>5471Y</td>
<td>Ondansetron SZ ODT, RX – ONDANSETRON, ONDANSETRON Tablet (orally disintegrating) 8 mg, 4</td>
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<tr>
<td>5473C</td>
<td>Ondansetron SZ ODT, RX – ONDANSETRON, ONDANSETRON Tablet (orally disintegrating) 8 mg, 10</td>
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<td>2242B</td>
<td>Paroxetine GH, GQ – PAROXETINE, paroxetine 20 mg tablet, 30</td>
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<td>8508T</td>
<td>Zabep, AL – RABEPRAZOLE, rabeprazole sodium 20 mg tablet: enteric, 30</td>
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<td>8509W</td>
<td>Zabep, AL – RABEPRAZOLE, rabeprazole sodium 20 mg tablet: enteric, 30</td>
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<tr>
<td>1978D</td>
<td>Ranitidine GH, GQ – RANITIDINE, ranitidine 150 mg tablet, 60</td>
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**Deletions**

**Deletion – Item**

- 2080L  CALCIPOTRIOL, calcipotriol 0.005% cream, 30 g *(Daivonex)*
- 1172Q  CHLORAMPHENICOL, chloramphenicol 0.5% ear drops, 5 mL *(Chloromycetin)*

**Deletion – Brand**

- 1210Q  Ciproxin 750, BN – CIPROFLOXACIN, ciprofloxacin 750 mg tablet, 14
- 8505P  Gabatine 100, QA – GABAPENTIN, gabapentin 100 mg capsule, 100
- 1834M  Gabatine 300, QA – GABAPENTIN, gabapentin 300 mg capsule, 100
- 1835N  Gabatine 400, QA – GABAPENTIN, gabapentin 400 mg capsule, 100
- 8559L  Gabatine 600, QA – GABAPENTIN, gabapentin 600 mg tablet, 100
- 8389M  Gabatine 800, QA – GABAPENTIN, gabapentin 800 mg tablet, 100
- 1596B  Ondaz, SZ – ONDANSETRON, ondansetron 4 mg/2 mL injection, 1 x 2 mL ampoule
- 8226Y  Ondaz, SZ – ONDANSETRON, ondansetron 4 mg/2 mL injection, 1 x 2 mL ampoule
- 1597C  Ondaz, SZ – ONDANSETRON, ondansetron 8 mg/4 mL injection, 1 x 4 mL ampoule
- 8227B  Ondaz, SZ – ONDANSETRON, ondansetron 8 mg/4 mL injection, 1 x 4 mL ampoule
- 9372G  Dilart HCT 80/12.5, AF – VALSARTAN + HYDROCHLOROTHIAZIDE, valsartan 80 mg + hydrochlorothiazide 12.5 mg tablet, 28

**Deletion – Equivalence Indicator**

- 9372G  Co-Diovan 80/12.5, NV – VALSARTAN + HYDROCHLOROTHIAZIDE, valsartan 80 mg + hydrochlorothiazide 12.5 mg tablet, 28

**Alterations**

**Alteration – Brand Name**

**From**

- 9012H  FonatPlus, AF – ALENDRONATE + COLECALCIFEROL, alendronate 70 mg + colecaltiferol 70 microgram tablet, 4

**To**

- 9012H  FonatPLUS, AF – ALENDRONATE + COLECALCIFEROL, alendronate 70 mg + colecaltiferol 70 microgram tablet, 4

**From**

- 9183H  Fonat Plus, AF – ALENDRONATE + COLECALCIFEROL, alendronate 70 mg + colecaltiferol 140 microgram
tablet, 4

To

9183H *FonatPLUS, AF – ALENDRONATE + COLECALCIFEROL*, alendronate 70 mg + coleccalciferol 140 microgram tablet, 4

From

2687K *Thioprine, AF – AZATHIOPRINE*, azathioprine 50 mg tablet, 100

To

2687K *Thioprine 50, AF – AZATHIOPRINE*, azathioprine 50 mg tablet, 100

**Alteration – Restriction**
The following items have additions, deletions or alterations to restrictions and/or notes.

8048N *ABCIXIMAB*, abciximab 10 mg/5 mL injection, 1 x 5 mL vial (*ReoPro*)

8954G *ADAPALENE + BENZOYL PEROXIDE*, adapalene 0.1% + benzoyl peroxide 2.5% gel, 30 g (*Epiduo*)

8955H *ADAPALENE + BENZOYL PEROXIDE*, adapalene 0.1% + benzoyl peroxide 2.5% gel, 30 g (*Epiduo*)

3408J *ADRENALINE*, adrenaline 150 microgram/0.3 mL injection, 1 x 0.3 mL syringe (*Anapen Junior*)

3409K *ADRENALINE*, adrenaline 300 microgram/0.3 mL injection, 1 x 0.3 mL syringe (*Anapen*)

8697R *ADRENALINE*, adrenaline 150 microgram/0.3 mL injection, 1 x 0.3 mL syringe (*EpiPen Jr.*)

8698T *ADRENALINE*, adrenaline 300 microgram/0.3 mL injection, 1 x 0.3 mL syringe (*EpiPen*)

8083K *APRaclonidine*, apraclonidine 0.5% eye drops, 10 mL (*Iopidine 0.5%*)

1115Q *BETAMETHASONE DIPROPIONATE*, betamethasone (as dipropionate) 0.05% cream, 15 g (*Diprosone, Eleupharat*)

1119X *BETAMETHASONE DIPROPIONATE*, betamethasone (as dipropionate) 0.05% ointment, 15 g (*Diprosone, Eleupharat*)

2812B *BETAMETHASONE VALERATE*, betamethasone (as valerate) 0.02% (200 microgram/g) cream, 100 g (*Antroquoril, Betnovate 1/5, Celestone-M, Cortival 1/5*)

2813C *BETAMETHASONE VALERATE*, betamethasone (as valerate) 0.05% (500 microgram/g) cream, 15 g (*Betnovate 1/2, Cortival 1/2*)

8439E *CELECOXIB*, celecoxib 100 mg capsule, 60 (*APO-Celecoxib, Blooms the Chemist Celecoxib, Celaxib, Celebrex, Celecoxib Actavis, Celecoxib GH, Celecoxib RBX, Celecoxib Sandoz, Celecoxib AN, Celexi, Chem mart Celecoxib, Kudeq, Terry White Chemists Celecoxib*)

8440F *CELECOXIB*, celecoxib 200 mg capsule, 30 (*APO-Celecoxib, Blooms the Chemist Celecoxib, Celaxib, Celebrex, Celecoxib AN, Celexi, Chem mart Celecoxib, Kudeq, Terry White Chemists Celecoxib*)

8132B *CLODRONATE*, clodronate sodium 400 mg capsule, 100 (*Bonefos*)

8265B *CLODRONATE*, clodronate sodium 800 mg tablet, 60 (*Bonefos 800 mg*)

1229Q *DALTEPARIN SODIUM*, dalteparin sodium 10 000 anti-Xa international units/mL injection, 10 x 1 mL syringes (*Fragmin*)

1296F *DALTEPARIN SODIUM*, dalteparin sodium 12 500 anti-Xa international units/0.5 mL injection, 10 x 0.5 mL syringes (*Fragmin*)

8641T *DALTEPARIN SODIUM*, dalteparin sodium 2500 anti-Xa international units/0.2 mL injection, 10 x 0.2 mL syringes (*Fragmin*)

8642W *DALTEPARIN SODIUM*, dalteparin sodium 5000 anti-Xa international units/0.2 mL injection, 10 x 0.2 mL syringes (*Fragmin*)

8643X *DALTEPARIN SODIUM*, dalteparin sodium 7500 anti-Xa international units/0.75 mL injection, 10 x 0.75 mL syringes (*Fragmin*)

8956J *DALTEPARIN SODIUM*, dalteparin sodium 7500 anti-Xa international units/0.75 mL injection, 10 x 0.75 mL
DALTEPARIN SODIUM, dalteparin sodium 10 000 anti-Xa international units/mL injection, 10 x 1 mL syringes (Fragmin)

DALTEPARIN SODIUM, dalteparin sodium 12 500 anti-Xa international units/0.5 mL injection, 10 x 0.5 mL syringes (Fragmin)

DALTEPARIN SODIUM, 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 (Fragmin)

EPLERENONE, eplerenone 25 mg tablet, 30 (Inspra)

EPLERENONE, eplerenone 50 mg tablet, 30 (Inspra)

ESSENTIAL AMINO ACIDS FORMULA, essential amino acids formula oral liquid: powder for, 2 x 200 g cans (Essential Amino Acid Mix)

ESSENTIAL AMINO ACIDS FORMULA WITH MINERALS AND VITAMIN C, essential amino acids formula with minerals and vitamin C oral liquid: powder for, 50 x 12.5 g sachets (EAA Supplement)

ETHACRYNIC ACID, ethacrynic acid 25 mg tablet, 100 (Edecrin)

FENTANYL, fentanyl 12 microgram/hour patch, 5 (Denpax)

FENTANYL, fentanyl 25 microgram/hour patch, 5 (Denpax)

FENTANYL, fentanyl 50 microgram/hour patch, 5 (Denpax)

FENTANYL, fentanyl 75 microgram/hour patch, 5 (Denpax)

FENTANYL, fentanyl 100 microgram/hour patch, 5 (Denpax)

FENTANYL, fentanyl 12 microgram/hour patch, 5 (Dutran 12, Fenpatch 12)

FENTANYL, fentanyl 25 microgram/hour patch, 5 (Dutran 25, Fenpatch 25)

FENTANYL, fentanyl 50 microgram/hour patch, 5 (Dutran 50, Fenpatch 50)

FENTANYL, fentanyl 75 microgram/hour patch, 5 (Dutran 75, Fenpatch 75)

FENTANYL, fentanyl 100 microgram/hour patch, 5 (Dutran 100, Fenpatch 100)

FENTANYL, fentanyl 12 microgram/hour patch, 5 (Durogesic 12, Fentanyl Sandoz)

FENTANYL, fentanyl 25 microgram/hour patch, 5 (Durogesic 25, Fentanyl Sandoz)

FENTANYL, fentanyl 50 microgram/hour patch, 5 (Durogesic 50, Fentanyl Sandoz)

FENTANYL, fentanyl 75 microgram/hour patch, 5 (Durogesic 75, Fentanyl Sandoz)

FENTANYL, fentanyl 100 microgram/hour patch, 5 (Durogesic 100, Fentanyl Sandoz)

FLUTICASONE + SALMETEROL, fluticasone propionate 100 microgram/actuation + salmeterol 50 microgram/actuation inhalation: powder for, 60 actuations (Seretide Accuhaler 100/50)

FLUTICASONE + SALMETEROL, fluticasone propionate 250 microgram/actuation + salmeterol 50 microgram/actuation inhalation: powder for, 60 actuations (Seretide Accuhaler 250/50)

FLUTICASONE + SALMETEROL, fluticasone propionate 500 microgram/actuation + salmeterol 50 microgram/actuation inhalation: powder for, 60 actuations (Seretide Accuhaler 500/50)

FLUTICASONE + SALMETEROL, fluticasone propionate 50 microgram/actuation + salmeterol 25 microgram/actuation inhalation: pressurised, 120 actuations (Seretide MDI 50/25)

FLUTICASONE + SALMETEROL, fluticasone propionate 125 microgram/actuation + salmeterol 25 microgram/actuation inhalation: pressurised, 120 actuations (Seretide MDI 125/25)

FUSIDATE, fusidate sodium 250 mg tablet, 36 (Fucidin)

HYDROCORTISONE ACETATE, hydrocortisone acetate 1% (10 mg/g) cream, 50 g (Cortic-DS 1%, Sigmacort)

HYDROCORTISONE ACETATE, hydrocortisone acetate 1% (10 mg/g) ointment, 50 g (Cortic-DS 1%, Sigmacort)
<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td>2887Y</td>
<td>HYDROCORTISONE ACETATE, hydrocortisone acetate 1% (10 mg/g) cream, 30 g (Cortic-DS 1%, Sigmacort)</td>
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<td>2888B</td>
<td>HYDROCORTISONE ACETATE, hydrocortisone acetate 1% (10 mg/g) ointment, 30 g (Cortic-DS 1%, Sigmacort)</td>
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<td>5111B</td>
<td>HYDROCORTISONE ACETATE, hydrocortisone acetate 1% (10 mg/g) cream, 30 g (Cortic-DS 1%, Sigmacort) (Dental)</td>
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<td>5112C</td>
<td>HYDROCORTISONE ACETATE, hydrocortisone acetate 1% (10 mg/g) ointment, 30 g (Cortic-DS 1%, Sigmacort) (Dental)</td>
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<td>5113D</td>
<td>HYDROCORTISONE ACETATE, hydrocortisone acetate 1% (10 mg/g) cream, 50 g (Cortic-DS 1%, Sigmacort) (Dental)</td>
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<td>5114E</td>
<td>HYDROCORTISONE ACETATE, hydrocortisone acetate 1% (10 mg/g) ointment, 50 g (Cortic-DS 1%, Sigmacort) (Dental)</td>
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<td>5115F</td>
<td>HYDROMORPHONE, hydromorphone hydrochloride 2 mg tablet, 20 (Dilauidid)(Dental)</td>
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<td>5116G</td>
<td>HYDROMORPHONE, hydromorphone hydrochloride 4 mg tablet, 20 (Dilauidid)(Dental)</td>
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<td>5117H</td>
<td>HYDROMORPHONE, hydromorphone hydrochloride 8 mg tablet, 20 (Dilauidid)(Dental)</td>
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<td>5132D</td>
<td>HYDROMORPHONE, hydromorphone hydrochloride 1 mg/mL oral liquid, 473 mL (Dilauidid)(Dental)</td>
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<td>8424J</td>
<td>HYDROMORPHONE, hydromorphone hydrochloride 1 mg/mL oral liquid, 473 mL (Dilauidid)</td>
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<td>8541M</td>
<td>HYDROMORPHONE, hydromorphone hydrochloride 2 mg tablet, 20 (Dilauidid)</td>
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<td>8542N</td>
<td>HYDROMORPHONE, hydromorphone hydrochloride 4 mg tablet, 20 (Dilauidid)</td>
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<td>HYDROMORPHONE, hydromorphone hydrochloride 8 mg tablet, 20 (Dilauidid)</td>
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<td>HYDROMORPHONE, hydromorphone hydrochloride 4 mg tablet: modified release, 14 tablets (Jurnista)</td>
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<td>9406C</td>
<td>HYDROMORPHONE, hydromorphone hydrochloride 8 mg tablet: modified release, 14 tablets (Jurnista)</td>
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<td>HYDROMORPHONE, hydromorphone hydrochloride 16 mg tablet: modified release, 14 tablets (Jurnista)</td>
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<td>HYDROMORPHONE, hydromorphone hydrochloride 32 mg tablet: modified release, 14 tablets (Jurnista)</td>
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<td>HYDROMORPHONE, hydromorphone hydrochloride 64 mg tablet: modified release, 14 tablets (Jurnista)</td>
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<td>IBANDRONIC ACID, ibandronic acid 50 mg tablet, 28 (Bondronat)</td>
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<td>1976B</td>
<td>ICATIBANT, ICATIBANT Injection 30 mg (as acetate) in 3 mL single use pre-filled syringe, 1 (Firazyr)</td>
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<tr>
<td>1606M</td>
<td>METHADONE, methadone hydrochloride 10 mg/mL injection, 5 x 1 mL ampoules (Physeptone)</td>
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<td>1609Q</td>
<td>METHADONE, methadone hydrochloride 10 mg tablet, 20 (Physeptone)</td>
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<tr>
<td>1621H</td>
<td>METRONIDAZOLE, metronidazole 400 mg tablet, 21 (Flagyl, Metrogyl 400, Metronide 400)</td>
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<tr>
<td>2313R</td>
<td>MINOXIDIL, minoxidil 10 mg tablet, 100 (Loniten)</td>
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<td>1646P</td>
<td>MORPHINE, morphine sulfate 30 mg tablet, 20 (Anamorph)</td>
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<td>1653B</td>
<td>MORPHINE, morphine sulfate 10 mg tablet: modified release, 28 tablets (MORPHINE MR APOTEX, MS Contin, Momex SR 10)</td>
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<td>MORPHINE, morphine sulfate 30 mg tablet: modified release, 28 tablets (MORPHINE MR APOTEX, MS Contin, Momex SR 30)</td>
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<td>1655D</td>
<td>MORPHINE, morphine sulfate 60 mg tablet: modified release, 28 tablets (MORPHINE MR APOTEX, MS Contin, Momex SR 60)</td>
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<td>1656E</td>
<td>MORPHINE, morphine sulfate 100 mg tablet: modified release, 28 tablets (APOTEX-MORPHINE MR, MS Contin, Momex SR 100)</td>
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<tr>
<td>2122Q</td>
<td>MORPHINE, morphine hydrochloride 2 mg/mL oral liquid, 200 mL (Ordine 2)</td>
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<td>2123R</td>
<td>MORPHINE, morphine hydrochloride 5 mg/mL oral liquid, 200 mL (Ordine 5)</td>
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<td>2124T</td>
<td>MORPHINE, morphine hydrochloride 10 mg/mL oral liquid, 200 mL (Ordine 10)</td>
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<td>2839K</td>
<td>MORPHINE, morphine Capsule 20 mg (containing sustained release pellets), 28 (Kapanol)</td>
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<td>2840L</td>
<td>MORPHINE, morphine Capsule 50 mg (containing sustained release pellets), 28 (Kapanol)</td>
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<tr>
<td>2841M</td>
<td>MORPHINE, morphine Capsule 100 mg (containing sustained release pellets), 28 (Kapanol)</td>
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<tr>
<td>5163R</td>
<td>MORPHINE, morphine sulfate 30 mg tablet, 20 (Anamorph)(Dental)</td>
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<tr>
<td>5237P</td>
<td>MORPHINE, morphine hydrochloride 2 mg/mL oral liquid, 200 mL (Ordine 2)(Dental)</td>
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<tr>
<td>5238Q</td>
<td>MORPHINE, morphine hydrochloride 5 mg/mL oral liquid, 200 mL (Ordine 5)(Dental)</td>
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MORPHINE, morphine hydrochloride 10 mg/mL oral liquid, 200 mL (Ordine 10)(Dental)

MORPHINE, morphine sulfate 5 mg tablet: modified release, 28 tablets (MS Contin)

MORPHINE, morphine Sachet containing controlled release granules for oral suspension, 30 mg per sachet, 28 (MS Contin Suspension 30 mg)

MORPHINE, morphine Sachet containing controlled release granules for oral suspension, 60 mg per sachet, 28 (MS Contin Suspension 60 mg)

MORPHINE, morphine sulfate 100 mg granules: modified release, 28 sachets (MS Contin Suspension 100 mg)

MORPHINE, morphine Capsule 10 mg (containing sustained release pellets), 28 (Kapanol)

MORPHINE, morphine sulfate 60 mg capsule: modified release, 14 capsules (MS Mono)

MORPHINE, morphine sulfate 90 mg capsule: modified release, 14 capsules (MS Mono)

MORPHINE, morphine sulfate 120 mg capsule: modified release, 14 capsules (MS Mono)

MORPHINE, morphine sulfate 10 mg tablet, 20 (Sevredol)

MORPHINE, morphine sulfate 20 mg tablet, 20 (Sevredol)

MOXONIDINE, moxonidine 200 microgram tablet, 30 (Physiotens)

MOXONIDINE, moxonidine 400 microgram tablet, 30 (Physiotens)

OXYCODONE, oxycodone 30 mg suppository, 12 (Proladone)

OXYCODONE, oxycodone hydrochloride 5 mg tablet, 20 (Endone)

OXYCODONE, oxycodone hydrochloride 5 mg/5 mL oral liquid, 250 mL (OxyNorm Liquid 5mg/5mL)(Dental)

OXYCODONE, oxycodone hydrochloride 5 mg capsule, 20 (OxyNorm)(Dental)

OXYCODONE, oxycodone 30 mg suppository, 12 (Proladone)(Dental)

OXYCODONE, oxycodone hydrochloride 5 mg tablet, 20 (Endone)(Dental)

OXYCODONE, oxycodone hydrochloride 10 mg capsule, 20 (OxyNorm)(Dental)

OXYCODONE, oxycodone hydrochloride 5 mg capsule, 20 (OxyNorm)

OXYCODONE, oxycodone hydrochloride 20 mg capsule, 20 (OxyNorm)

OXYCODONE, oxycodone hydrochloride 5 mg/5 mL oral liquid, 250 mL (OxyNorm Liquid 5mg/5mL)

OXYCODONE + NALOXONE, oxycodone hydrochloride 5 mg + naloxone hydrochloride 2.5 mg tablet: modified release, 28 tablets (Targin 5/2.5mg)

OXYCODONE + NALOXONE, oxycodone hydrochloride 10 mg + naloxone hydrochloride 5 mg tablet: modified release, 28 tablets (Targin 10/5mg)

OXYCODONE + NALOXONE, oxycodone hydrochloride 20 mg + naloxone hydrochloride 10 mg tablet: modified release, 28 tablets (Targin 20/10mg)

OXYCODONE + NALOXONE, oxycodone hydrochloride 40 mg + naloxone hydrochloride 20 mg tablet: modified release, 28 tablets (Targin 40/20mg)

PARACETAMOL, paracetamol 500 mg tablet, 100 (APO-Paracetamol, Febridol, Generic Health Pty Ltd, Panamax, Paracetamol (Sandoz), Paralgin, Parapane)(Dental)

PARACETAMOL, paracetamol 500 mg tablet, 100 (APO-Paracetamol, Febridol, Generic Health Pty Ltd, Panamax, Paracetamol (Sandoz), Paralgin, Parapane)

PARACETAMOL, paracetamol 665 mg tablet: modified release, 96 tablets (Osteomol 665 Paracetamol, Panadol Osteo)

PARACETAMOL + CODEINE, CODEINE PHOSPHATE with PARACETAMOL Tablet 30 mg-500 mg, 20 (APO-Paracetamol/Codeine 500/30, Codalgin Forte, Codapane Forte, Comfarol Forte, Panadeine Forte, Paracetamol/Codeine GH 500/30, Prodeine Forte)
8785J PARACETAMOL + CODEINE, CODEINE PHOSPHATE with PARACETAMOL Tablet 30 mg-500 mg, 20 (APO-Paracetamol/Codeine 500/30, Codalgin Forte, Codapane Forte, Comfarol Forte, Panadeine Forte, Paracetamol/Codeine GH 500/30, Prodeine Forte)

10212L PEGINTERFERON BETA-1A, peginterferon beta-1a 125 microgram/0.5 mL injection, 2 x 0.5 mL injection devices (Plegridy)

10218T PEGINTERFERON BETA-1A, peginterferon beta-1a 63 microgram/0.5 mL injection [0.5 mL injection device] (&) peginterferon beta-1a 94 microgram/0.5 mL injection [0.5 mL injection device], 1 pack (Plegridy)

10220X PEGINTERFERON BETA-1A, peginterferon beta-1a 125 microgram/0.5 mL injection, 2 x 0.5 mL injection devices (Plegridy)

2997R SALCATONIN, salcatoconin 100 international units/mL injection, 5 x 1 mL ampoules (Miacalcic 100)

10086W SAPROPTERIN, sapropterin dihydrochloride 100 mg tablet: soluble, 30 tablets (Kuvan)

8221Q TIAGABINE, tiagabine 5 mg tablet, 50 (Gabitril)

8222R TIAGABINE, tiagabine 10 mg tablet, 50 (Gabitril)

8223T TIAGABINE, tiagabine 15 mg tablet, 50 (Gabitril)

2667J VIGABATRIN, vigabatrin 500 mg tablet, 100 (Sabril)

2668K VIGABATRIN, vigabatrin 500 mg oral liquid: powder for, 60 x 500 mg sachets (Sabril)

9328Y VITAMINS, MINERALS AND TRACE ELEMENTS WITH CARBOHYDRATE, vitamins, minerals and trace elements with carbohydrate oral liquid: powder for, 200 g (Paediatric Seravit)

8587Y WHEY PROTEIN FORMULA SUPPLEMENTED WITH AMINO ACIDS, VITAMINS AND MINERALS, AND LOW IN PROTEIN, PHOSPHATE, POTASSIUM AND LACTOSE, whey protein formula supplemented with amino acids, vitamins and minerals, and low in protein, phosphate, potassium and lactose oral liquid: powder for, 400 g (Kindergen)

Alteration – Restriction Level

10212L PEGINTERFERON BETA-1A, peginterferon beta-1a 125 microgram/0.5 mL injection, 2 x 0.5 mL injection devices (Plegridy) From authority-required To streamlined

10218T PEGINTERFERON BETA-1A, peginterferon beta-1a 63 microgram/0.5 mL injection [0.5 mL injection device] (&) peginterferon beta-1a 94 microgram/0.5 mL injection [0.5 mL injection device], 1 pack (Plegridy) From authority-required To streamlined

10220X PEGINTERFERON BETA-1A, peginterferon beta-1a 125 microgram/0.5 mL injection, 2 x 0.5 mL injection devices (Plegridy) From authority-required To streamlined

Advance Notices

1 July 2015

Deletion – Brand

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

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

1 August 2015

Deletion – Item

2873F Invokana, JC – CANAGLIFLOZIN, canagliflozin 100 mg tablet, 30

2987F Invokana, JC – CANAGLIFLOZIN, canagliflozin 300 mg tablet, 30

9157Y Sensipar, AN – CINACALCET, cinacalcet 30 mg tablet, 28

9158B Sensipar, AN – CINACALCET, cinacalcet 60 mg tablet, 28

9159C Sensipar, AN – CINACALCET, cinacalcet 90 mg tablet, 28

Highly Specialised Drugs Program (Private Hospital)

Additions

Addition – Item

10263E ANAKINRA, anakinra 100 mg/0.67 mL injection, 28 x 0.67 mL syringes (Kineret)

Alterations

Schedule of Pharmaceutical Benefits 11
**Alteration – Restriction**

10175M  **IVACAFTOR**, ivacaftor 150 mg tablet, 56 *(Kalydeco)*

**Advance Notices**

1 August 2015

**Deletion – Item**

9625N  **Sensipar, AN – CINACALCET**, cinacalcet 30 mg tablet, 28

9626P  **Sensipar, AN – CINACALCET**, cinacalcet 60 mg tablet, 28

9627Q  **Sensipar, AN – CINACALCET**, cinacalcet 90 mg tablet, 28

**Highly Specialised Drugs Program (Public Hospital)**

**Additions**

**Addition – Item**

10264F  **ANAKINRA**, anakinra 100 mg/0.67 mL injection, 28 x 0.67 mL syringes *(Kineret)*

**Alterations**

**Alteration – Restriction**

10170G  **IVACAFTOR**, ivacaftor 150 mg tablet, 56 *(Kalydeco)*

**Advance Notices**

1 August 2015

**Deletion – Item**

5621W  **Sensipar, AN – CINACALCET**, cinacalcet 30 mg tablet, 28

5622X  **Sensipar, AN – CINACALCET**, cinacalcet 60 mg tablet, 28

5623Y  **Sensipar, AN – CINACALCET**, cinacalcet 90 mg tablet, 28

**Palliative Care**

**Alterations**

**Alteration – Restriction**

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

5407N  **FENTANYL**, FENTANYL Lozenge 200 micrograms (as citrate), 30 *(Actiq)*

5408P  **FENTANYL**, FENTANYL Lozenge 400 micrograms (as citrate), 30 *(Actiq)*

5409Q  **FENTANYL**, FENTANYL Lozenge 600 micrograms (as citrate), 30 *(Actiq)*

5410R  **FENTANYL**, FENTANYL Lozenge 800 micrograms (as citrate), 30 *(Actiq)*

5411T  **FENTANYL**, FENTANYL Lozenge 1200 micrograms (as citrate), 30 *(Actiq)*

5412W  **FENTANYL**, FENTANYL Lozenge 1600 micrograms (as citrate), 30 *(Actiq)*

5399E  **METHADONE**, methadone hydrochloride 5 mg/mL oral liquid, 200 mL *(Aspen Methadone Syrup)*

5400F  **METHADONE**, methadone hydrochloride 5 mg/mL oral liquid, 200 mL *(Aspen Methadone Syrup)*

5391R  **MORPHINE**, morphine sulfate 200 mg tablet: modified release, 28 tablets *(MS Contin)*

5392T  **MORPHINE**, morphine sulfate 200 mg tablet: modified release, 28 tablets *(MS Contin)*

5393W  **MORPHINE**, morphine sulfate 10 mg tablet, 20 *(Sevredol)*

5394X  **MORPHINE**, morphine sulfate 20 mg tablet, 20 *(Sevredol)*

5395Y  **MORPHINE**, morphine sulfate 10 mg tablet, 20 *(Sevredol)*

5396B  **MORPHINE**, morphine sulfate 20 mg tablet, 20 *(Sevredol)*

5319Y  **PARACETAMOL**, paracetamol 500 mg suppository, 24 *(Panadol)*

5320B  **PARACETAMOL**, paracetamol 500 mg suppository, 24 *(Panadol)*

5343F  **PARACETAMOL**, paracetamol 665 mg tablet: modified release, 96 tablets *(Osteomol 665 Paracetamol, Panadol Osteo)*

5344G  **PARACETAMOL**, paracetamol 665 mg tablet: modified release, 96 tablets *(Osteomol 665 Paracetamol, Panadol*
Repatriation Pharmaceutical Benefits
Additions

**Addition – Brand**

<table>
<thead>
<tr>
<th>Code</th>
<th>Product</th>
<th>Brand and Details</th>
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<tbody>
<tr>
<td>2194L</td>
<td>Alendronate plus D3-DRLA, RZ</td>
<td>ALENDRONATE + COLECALCIFEROL, alendronate 70 mg + colecalciferol 70 microgram tablet, 4</td>
</tr>
<tr>
<td>2194L</td>
<td>FonatPLUS, AF</td>
<td>ALENDRONATE + COLECALCIFEROL, alendronate 70 mg + colecalciferol 70 microgram tablet, 4</td>
</tr>
<tr>
<td>2224C</td>
<td>FonatPLUS, AF</td>
<td>ALENDRONATE + COLECALCIFEROL, alendronate 70 mg + colecalciferol 140 microgram tablet, 4</td>
</tr>
<tr>
<td>4198Y</td>
<td>Chemists’ Own Laxative with Senna, AS</td>
<td>DOCUSATE + SENNOSIDES, docusate sodium 50 mg + sennosides 11.27 mg tablet, 90</td>
</tr>
<tr>
<td>4198Y</td>
<td>Colaxsen, QA</td>
<td>DOCUSATE + SENNOSIDES, docusate sodium 50 mg + sennosides 11.27 mg tablet, 90</td>
</tr>
<tr>
<td>4584G</td>
<td>Sildenafil Actavis, UA</td>
<td>SILDENAFIL, sildenafil 25 mg tablet, 4</td>
</tr>
<tr>
<td>4584G</td>
<td>Vedafil, AF</td>
<td>SILDENAFIL, sildenafil 25 mg tablet, 4</td>
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<td>4585H</td>
<td>Sildenafil Actavis, UA</td>
<td>SILDENAFIL, sildenafil 50 mg tablet, 4</td>
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<tr>
<td>4585H</td>
<td>Vedafil, AF</td>
<td>SILDENAFIL, sildenafil 50 mg tablet, 4</td>
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<tr>
<td>4586J</td>
<td>Sildenafil Actavis, UA</td>
<td>SILDENAFIL, sildenafil 100 mg tablet, 4</td>
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<tr>
<td>4586J</td>
<td>Vedafil, AF</td>
<td>SILDENAFIL, sildenafil 100 mg tablet, 4</td>
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<tr>
<td>4522B</td>
<td>APO-Zopiclone, TX</td>
<td>ZOPICLONE, zopiclone 7.5 mg tablet, 30</td>
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<tr>
<td>4522B</td>
<td>Chem mart Zopiclone, CH</td>
<td>ZOPICLONE, zopiclone 7.5 mg tablet, 30</td>
</tr>
<tr>
<td>4522B</td>
<td>Terry White Chemists Zopiclone, TW</td>
<td>ZOPICLONE, zopiclone 7.5 mg tablet, 30</td>
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**Addition – Equivalence Indicator**

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<th>Code</th>
<th>Product</th>
<th>Brand and Details</th>
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</thead>
<tbody>
<tr>
<td>2194L</td>
<td>Fosamax Plus, MK</td>
<td>ALENDRONATE + COLECALCIFEROL, alendronate 70 mg + colecalciferol 70 microgram tablet, 4</td>
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**Deletions**

**Deletion – Brand**

<table>
<thead>
<tr>
<th>Code</th>
<th>Product</th>
<th>Brand and Details</th>
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<tbody>
<tr>
<td>4591P</td>
<td>Gabatine 100, QA</td>
<td>GABAPENTIN, gabapentin 100 mg capsule, 100</td>
</tr>
<tr>
<td>4592Q</td>
<td>Gabatine 300, QA</td>
<td>GABAPENTIN, gabapentin 300 mg capsule, 100</td>
</tr>
<tr>
<td>4593R</td>
<td>Gabatine 400, QA</td>
<td>GABAPENTIN, gabapentin 400 mg capsule, 100</td>
</tr>
<tr>
<td>4594T</td>
<td>Gabatine 600, QA</td>
<td>GABAPENTIN, gabapentin 600 mg tablet, 100</td>
</tr>
<tr>
<td>4595W</td>
<td>Gabatine 800, QA</td>
<td>GABAPENTIN, gabapentin 800 mg tablet, 100</td>
</tr>
</tbody>
</table>
About the Schedule

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

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

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

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

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

Symbols Used in the Schedule

* An asterisk in the dispensed price column indicates that the manufacturer's pack does not coincide with the maximum quantity

‡ A double dagger in the maximum quantity column indicates where the maximum quantity has been determined to match the manufacturer's pack. These packs cannot be broken and the maximum quantity should be supplied and claimed

# A gauge in the dispensed price column indicates that the product is not preconstituted and that the dispensed price therefore included a dispensing fee and where appropriate, an amount for purified water

a or b Located immediately before brand names of an item indicates that the brands are equivalent for the purposes of substitution. These brands may be interchanged without differences in clinical effect

B Located immediately before an amount in the premium column indicates a brand premium which applies to that particular brand of the item

T Located immediately before an amount in the premium column indicates a therapeutic group premium which applies to that particular item.

S Located immediately before an amount in the premium column indicates a special patient contribution which applies to that particular item.

NM Indicates that the item can be prescribed by an authorised nurse practitioner

MW Indicates that the item can be prescribed by an authorised midwife

OP Indicates that the item can be prescribed by an authorised optometrist

DP Indicates that the item can be prescribed by an authorised dental practitioner

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.

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

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

Authority required (STREAMLINED) – authority can be sought electronically.
Pharmaceutical Benefits Schedules
Prescriber Bag
- **ADRENALINE**
  adrenaline 1 in 1000 (1 mg/mL) injection, 5 x 1 mL ampoules

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>DPMQ $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>20.68</td>
<td>Link Medical Products Pty Ltd [LM]</td>
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</table>

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

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>DPMQ $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>1</td>
<td>20.88</td>
<td>Pfizer Australia Pty Ltd [PF]</td>
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- **BENZTROPINE**
  benztropine mesylate 2 mg/2 mL injection, 5 x 2 mL ampoules

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<th>Max Qty Packs</th>
<th>DPMQ $</th>
<th>Brand Name and Manufacturer</th>
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<tr>
<td>1</td>
<td>103.93</td>
<td>Cogentin [FK]</td>
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- **BENZYLPCNILLIN**
  benzylpenicillin 600 mg injection, 1 x 600 mg vial

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<th>Max Qty Packs</th>
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<tbody>
<tr>
<td>5</td>
<td>*31.96</td>
<td>BenPen [CS]</td>
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  OR

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

<table>
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<th>Max Qty Packs</th>
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<tr>
<td>1</td>
<td>92.56</td>
<td>Cilicaine [QA]</td>
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- **BENZYLPCNILLIN**
  benzylpenicillin 3 g injection, 1 x 3 g vial

<table>
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<tbody>
<tr>
<td>1</td>
<td>15.44</td>
<td>BenPen [CS]</td>
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- **CHLORPROMAZINE**
  chlorpromazine hydrochloride 50 mg/2 mL injection, 10 x 2 mL ampoules

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
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<th>Brand Name and Manufacturer</th>
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<tr>
<td>1</td>
<td>20.82</td>
<td>Largactil [SW]</td>
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  OR

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

<table>
<thead>
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<th>Max Qty Packs</th>
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<tr>
<td>1</td>
<td>22.62</td>
<td>Serenate [QA]</td>
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- **CLONAZEPAM**
  clonazepam 2.5 mg/mL oral liquid, 10 mL

<table>
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<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>‡1</td>
<td>11.07</td>
<td>Rivotril [RO]</td>
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</table>
### DEXAMETHASONE SODIUM PHOSPHATE

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

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
<th>DPMQ $</th>
<th>Brand Name and Manufacturer</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>1</td>
<td>17.96</td>
<td>&quot;Dexamethone [AF]&quot;</td>
<td>&quot;Hospira Pty Limited [HH]&quot;</td>
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**OR**

### HYDROCORTISONE SODIUM SUCCINATE

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

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
<th>DPMQ $</th>
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<tr>
<td>2</td>
<td>*18.04</td>
<td>Solu-Cortef [PF]</td>
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**OR**

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

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
<th>DPMQ $</th>
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<tbody>
<tr>
<td>1</td>
<td>16.83</td>
<td>Solu-Cortef [PF]</td>
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</table>

### DIAZEPAM

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

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
<th>DPMQ $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>13.68</td>
<td>Hospira Pty Limited [HH]</td>
</tr>
</tbody>
</table>

### DIPHTHERIA TOXOID + TETANUS TOXOID

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

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
<th>DPMQ $</th>
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<tbody>
<tr>
<td>1</td>
<td>144.59</td>
<td>MassBiologics tetanus and diphtheria toxoids adsorbed [CS]</td>
</tr>
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</table>

**OR**

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

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
<th>DPMQ $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>2</td>
<td>*144.60</td>
<td>ADT Booster [CS]</td>
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### FRUSEMIDE

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

<table>
<thead>
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<th>Max.Qty Packs</th>
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<tr>
<td>1</td>
<td>8.63</td>
<td>&quot;Frusemide-Claris [AE]&quot;</td>
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<td></td>
<td></td>
<td>&quot;Lasix [SW]&quot;</td>
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</table>

### GLUCAGON HYDROCHLORIDE

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

<table>
<thead>
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<th>Max.Qty Packs</th>
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<td>1</td>
<td>50.55</td>
<td>GlucaGen Hypokit [NO]</td>
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### GLYCERYL TRINITRATE

glyceryl trinitrate 400 microgram/actuation spray, 200 actuations

<table>
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<th>DPMQ $</th>
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<tr>
<td>1</td>
<td>20.47</td>
<td>Nitrolingual Pumpspray [SW]</td>
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### HYOSCINE BUTYLBROMIDE

hyoscine butylibromide 20 mg/mL injection, 5 x 1 mL ampoules

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<td>1</td>
<td>24.55</td>
<td>Buscopan [BY]</td>
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## LIGNOCAINE
lignocaine hydrochloride anhydrous 1% (50 mg/5 mL) injection, 5 x 5 mL ampoules

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<tr>
<td>10209H</td>
<td>1</td>
<td>37.67</td>
<td>Pfizer Australia Pty Ltd [PF]</td>
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## METHOXYFLURANE
methoxyflurane 999.9 mg/g inhalation: solution, 1 x 3 mL bottle

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<tr>
<td>3489P</td>
<td>1</td>
<td>45.12</td>
<td>Penthrox [DV]</td>
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## METOCLOPRAMIDE
metoclopramide hydrochloride 10 mg/2 mL injection, 10 x 2 mL ampoules

<table>
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<td>3476Y</td>
<td>1</td>
<td>13.33</td>
<td>Maxolon [IA]</td>
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OR

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

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<td>3477B</td>
<td>1</td>
<td>17.89</td>
<td>Stemetil [SW]</td>
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## MIDDZOLAM
midazolam 5 mg/mL injection, 10 x 1 mL ampoules

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<td>10178Q</td>
<td>1</td>
<td>38.91</td>
<td>Pfizer Australia Pty Ltd [PF]</td>
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## MORPHINE
morphine sulfate 15 mg/mL injection, 5 x 1 mL ampoules

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<td>3479D</td>
<td>1</td>
<td>17.30</td>
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OR

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

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<td>3480E</td>
<td>1</td>
<td>19.43</td>
<td>Hospira Pty Limited [HH]</td>
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## NALOXONE
naloxone hydrochloride 400 microgram/mL syringe

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<tr>
<td>2200T</td>
<td>10</td>
<td>*203.56</td>
<td>Naloxone minijet [UC]</td>
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## OXYTOCIN
oxytocin 10 international units/mL injection, 5 x 1 mL ampoules

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<td>10251M</td>
<td>1</td>
<td>61.76</td>
<td>Oxytocin Sandoz [SZ]</td>
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## PHYTOMENADIONE
phytomenadione 10 mg/mL injection, 5 x 1 mL ampoules

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<td>10213M</td>
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<td>22.27</td>
<td>Konakion MM [RO]</td>
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## PROMETHAZINE
promethazine hydrochloride 50 mg/2 mL injection, 5 x 2 mL ampoules

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<td>2</td>
<td>*30.58</td>
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### SALBUTAMOL

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

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<td>☑️</td>
<td>‡1</td>
<td>10.45</td>
<td>‡1 APO-Salbutamol Inhaler [TX]</td>
<td>☑️ Asmol CFC-free [AL]</td>
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<tr>
<td>☑️</td>
<td>11.62</td>
<td>11.62</td>
<td>☑️ Ventolin CFC-free [GK]</td>
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**OR**

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

<table>
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<tr>
<th>3496B</th>
<th>Max.Qty Packs</th>
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<tbody>
<tr>
<td>☑️</td>
<td>‡1</td>
<td>11.36</td>
<td>‡1 APO-Salbutamol [TX]</td>
<td>☑️ Asmol 2.5 uni-dose [AF]</td>
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<tr>
<td>☑️</td>
<td>11.96</td>
<td>11.96</td>
<td>☑️ Butamol 2.5 [QA]</td>
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<tr>
<td>☑️</td>
<td>11.96</td>
<td>11.96</td>
<td>☑️ Pharmacor Salbutamol 2.5 [CR]</td>
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<tr>
<td>☑️</td>
<td>11.96</td>
<td>11.96</td>
<td>☑️ Salbutamol-GA [GN]</td>
<td></td>
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<tr>
<td>☑️</td>
<td>11.96</td>
<td>11.96</td>
<td>☑️ Ventolin Nebules [GK]</td>
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</table>

### SALBUTAMOL

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

<table>
<thead>
<tr>
<th>3497C</th>
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<td>☑️</td>
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<td>☑️ Butamol 5 [QA]</td>
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<tr>
<td>☑️</td>
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<td>11.60</td>
<td>☑️ Pharmacor Salbutamol 5 [CR]</td>
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<tr>
<td>☑️</td>
<td>11.60</td>
<td>11.60</td>
<td>☑️ Salbutamol-GA [GN]</td>
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<tr>
<td>☑️</td>
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<td>11.60</td>
<td>☑️ Ventolin Nebules [GK]</td>
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</table>

### TRAMADOL

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

<table>
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<th>3484J</th>
<th>Max.Qty Packs</th>
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<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>☑️</td>
<td>1</td>
<td>11.92</td>
<td>☑️ Tramadol ACT [GN]</td>
<td>☑️ Tramadol Sandoz [SZ]</td>
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<tr>
<td>☑️</td>
<td>11.92</td>
<td>11.92</td>
<td>☑️ Tramal 100 [CS]</td>
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<td>ANABOLIC STEROIDS</td>
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Antiinfectives and antiseptics for local oral treatment

- **AMPHOTERICIN B**
  - amphotericin B 10 mg lozenge, 20
    - 2931G
    - Max Qty Packs: 1
    - No. of Rpts: 1
    - Premium $: 12.37
    - DPMQ $: 13.52
    - MRVSN $: 13.52
    - Brand Name and Manufacturer: Fungilin [QA]
  - amphotericin B 10 mg lozenge, 20
    - 3306B
    - Max Qty Packs: 1
    - No. of Rpts: 1
    - Premium $: 12.37
    - DPMQ $: 13.52
    - MRVSN $: 13.52
    - Brand Name and Manufacturer: Fungilin [QA]

- **NYSTATIN**
  - nystatin 100 000 international units/mL oral liquid, 24 mL
    - 3033P
    - Max Qty Packs: 1
    - No. of Rpts: 1
    - Premium $: 11.48
    - DPMQ $: 12.63
    - MRVSN $: 12.63
    - Brand Name and Manufacturer: Mycostatin [FM]
    - Mycostatin [FM]: 3.01
    - Nilstat [QA]: 14.49
    - Nilstat [QA]: 12.63
    - Nilstat [QA]: 3.01

- **BENZYMADINE**
  - Restricted benefit
  - Radiation induced mucositis
  - benzydamine hydrochloride 0.15% mouthwash, 500 mL
    - 1121B
    - Max Qty Packs: 1
    - No. of Rpts: 1
    - Premium $: 22.60
    - DPMQ $: 23.75
    - Brand Name and Manufacturer: Difflam [IA]
  - benzydamine hydrochloride 0.15% mouthwash, 500 mL
    - 5032W
    - Max Qty Packs: 1
    - No. of Rpts: 1
    - Premium $: 22.60
    - DPMQ $: 23.75
    - Brand Name and Manufacturer: Difflam [IA]

**DRUGS FOR ACID RELATED DISORDERS**

- **ANTACIDS**
  - Combinations and complexes of aluminium, calcium and magnesium compounds
  - **ALUMINIUM HYDROXIDE + MAGNESIUM HYDROXIDE + MAGNESIUM TRISILICATE**
    - aluminium hydroxide 250 mg/5 mL + magnesium hydroxide 120 mg/5 mL + magnesium trisilicate 120 mg/5 mL oral liquid, 500 mL
      - 2159P
      - Max Qty Packs: 2
      - No. of Rpts: 5
      - Premium $: 18.04
      - DPMQ $: 19.19
      - Brand Name and Manufacturer: Gastrogel [FM]
  - **ALUMINIUM HYDROXIDE WITH MAGNESIUM HYDROXIDE**
    - **ALUMINIUM HYDROXIDE WITH MAGNESIUM HYDROXIDE**
    - Oral suspension 200 mg-200 mg per 5 mL, 500 mL, 1
      - 2157M
      - Max Qty Packs: 2
      - No. of Rpts: 5
      - Premium $: 18.04
      - DPMQ $: 19.19
      - Brand Name and Manufacturer: Mylanta P [JT]

**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.
### ALIMENTARY TRACT AND METABOLISM

#### Schedule of Pharmaceutical Benefits

<table>
<thead>
<tr>
<th>Cimetidine 400 mg tablet, 60</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Brand Name and Manufacturer</strong></td>
</tr>
<tr>
<td>Magicul 400 [AF]</td>
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<table>
<thead>
<tr>
<th>FAMOTIDINE</th>
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</thead>
<tbody>
<tr>
<td><strong>Note</strong></td>
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<tr>
<td>Helicobacter pylori eradication therapy should be considered prior to commencing initial treatment of peptic ulcer with this drug.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Famotidine 20 mg tablet, 60</th>
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<tbody>
<tr>
<td><strong>Brand Name and Manufacturer</strong></td>
</tr>
<tr>
<td>Ausfam 20 [QA]</td>
</tr>
<tr>
<td>Chem mart Famotidine [CH]</td>
</tr>
<tr>
<td>Famotidine AN [EA]</td>
</tr>
<tr>
<td>GenRx Famotidine [GX]</td>
</tr>
<tr>
<td>Pepzan [GN]</td>
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<table>
<thead>
<tr>
<th>Famotidine 40 mg tablet, 30</th>
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<tbody>
<tr>
<td><strong>Brand Name and Manufacturer</strong></td>
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<td>Famotidine AN [EA]</td>
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<tr>
<td>GenRx Famotidine [GX]</td>
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<tr>
<td>Pepzan [GN]</td>
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<tr>
<td>Terry White Chemists Famotidine [TW]</td>
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<table>
<thead>
<tr>
<th>NIZATIDINE</th>
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<tbody>
<tr>
<td><strong>Note</strong></td>
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<tr>
<td>Helicobacter pylori eradication therapy should be considered prior to commencing initial treatment of peptic ulcer with this drug.</td>
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<table>
<thead>
<tr>
<th>Nizatidine 150 mg capsule, 60</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Brand Name and Manufacturer</strong></td>
</tr>
<tr>
<td>Nizac [LN]</td>
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<tr>
<td>Tacidine [AF]</td>
</tr>
<tr>
<td>Tazac [AS]</td>
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</table>

<table>
<thead>
<tr>
<th>Nizatidine 300 mg capsule, 30</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Brand Name and Manufacturer</strong></td>
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<tr>
<td>Nizac [LN]</td>
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<tr>
<td>Tacidine [AF]</td>
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<td>Tazac [AS]</td>
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<tbody>
<tr>
<td><strong>Note</strong></td>
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<td>Helicobacter pylori eradication therapy should be considered prior to commencing initial treatment of peptic ulcer with this drug.</td>
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<table>
<thead>
<tr>
<th>Ranitidine 150 mg tablet, 60</th>
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<tbody>
<tr>
<td><strong>Brand Name and Manufacturer</strong></td>
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<tr>
<td>APO-Ranitidine [TX]</td>
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<td>Chem mart Ranitidine [CH]</td>
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<td>Rani 2 [AF]</td>
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<td>Ranitidine GH [GQ]</td>
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<td>Ranoxyl [GN]</td>
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<td>Ulcaid [RA]</td>
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<td>Zantac [AS]</td>
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<table>
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<th>Ranitidine 150 mg tablet: effervescent, 30</th>
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<tbody>
<tr>
<td><strong>Brand Name and Manufacturer</strong></td>
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<td>Zantac [AS]</td>
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<tr>
<th>Ranitidine 150 mg/10 mL oral liquid, 300 mL</th>
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<td><strong>Brand Name and Manufacturer</strong></td>
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<td>Zantac Syrup [AS]</td>
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<th>Ranitidine 300 mg tablet, 30</th>
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<tr>
<td><strong>Brand Name and Manufacturer</strong></td>
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<tr>
<td>APO-Ranitidine [TX]</td>
</tr>
<tr>
<td>Ausran [QA]</td>
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</table>
**Proton pump inhibitors**

### ESOMEPRAZOLE

**Restricted benefit**

Healing of gastro-oesophageal reflux disease

**Note**

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

**esomeprazole 40 mg tablet: enteric, 30 tablets**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
<th>Brand Name and Manufacturer</th>
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<tr>
<td>8601Q</td>
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<td>38.32</td>
<td>37.70</td>
<td>* Esomeprazole Apotex [TX]</td>
<td>* Esomeprazole GxP [AF]</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Esomeprazole RBX [RA]</td>
<td>* Nexium [AP]</td>
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</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.

**esomeprazole 40 mg tablet: enteric, 30 tablets**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
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<td></td>
<td></td>
<td>* Esomeprazole RBX [RA]</td>
<td>* Nexium [AP]</td>
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</tbody>
</table>

### ESOMEPRAZOLE

**Restricted benefit**

Initial treatment of gastric ulcer

**Note**

Helicobacter pylori eradication therapy should be considered.

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

**esomeprazole 20 mg tablet: enteric, 30 tablets**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
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<td></td>
<td></td>
<td>* Esomeprazole RBX [RA]</td>
<td>* Nexium [AP]</td>
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</tbody>
</table>

### 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**

No applications for increased maximum quantities will be authorised.

**esomeprazole 20 mg tablet: enteric, 30 tablets**

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<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
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<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>8600P</td>
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<td>5</td>
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<td>25.37</td>
<td>* Esomeprazole Apotex [TX]</td>
<td>* Esomeprazole GxP [AF]</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Esomeprazole RBX [RA]</td>
<td>* Nexium [AP]</td>
</tr>
</tbody>
</table>

### LANSOPRAZOLE

**Restricted benefit**

Gastro-oesophageal reflux disease

**Restricted benefit**

| * Chem mart Ranitidine [CH] | * GenRx Ranitidine [GX] |
| * Rani 2 [AF] | * Ranitidine GH [GQ] |
| * Ranitidine Sandoz [SZ] | * Ranoxyl [GN] |
| * Terry White Chemists Ranitidine [TW] | |
Scleroderma oesophagus

**Lansoprazole 15 mg capsule: enteric, 30**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
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<tr>
<td>8198L</td>
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<td>13.95</td>
<td>15.10 Zopral [AF]</td>
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</table>

**Lansoprazole 15 mg tablet: orally disintegrating, 28 tablets**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
</table>

**LANSOPRAZOLE**

**Restricted benefit**
Initial treatment of peptic ulcer

**Note**
Helicobacter pylori eradication therapy should be considered.
No applications for increased repeats will be authorised.
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.

**Lansoprazole 30 mg capsule: enteric, 28**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
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<td>18.75</td>
<td>19.90 * APO-Lansoprazole ODT [TX] * Zopral ODT [AF] * Lanzopran [RA]</td>
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</table>

**Lansoprazole 30 mg tablet: orally disintegrating, 28 tablets**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
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<tr>
<td>9477T</td>
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<td>1</td>
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<td>18.75</td>
<td>19.90 * APO-Lansoprazole ODT GH [GQ] * Zopral ODT [AF] * Zoton FasTabs [PF]</td>
</tr>
</tbody>
</table>

**LANSOPRAZOLE**

**Restricted benefit**
Gastro-oesophageal reflux disease

**Restricted benefit**
Scleroderma oesophagus

**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.

**Lansoprazole 30 mg capsule: enteric, 28**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
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<th>Brand Name and Manufacturer</th>
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**Lansoprazole 30 mg tablet: orally disintegrating, 28 tablets**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
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<tr>
<td>9478W</td>
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<td>18.75</td>
<td>19.90 * APO-Lansoprazole ODT GH [GQ] * Zopral ODT [AF] * Zoton FasTabs [PF]</td>
</tr>
</tbody>
</table>

**OMEPRAZOLE**

**Restricted benefit**
Gastro-oesophageal reflux disease

**Restricted benefit**
Scleroderma oesophagus

**Restricted benefit**
Zollinger-Ellison syndrome

**Omeprazole 10 mg tablet: enteric, 30 tablets**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
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<tbody>
<tr>
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<td>11.54</td>
<td>12.69 Losec Tablets [AP]</td>
</tr>
</tbody>
</table>

**OMEPRAZOLE**

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

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

### OMEPRAZOLE

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

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

### PANTOPRAZOLE

#### Restricted benefit
- Initial treatment of peptic ulcer

#### Note
Helicobacter pylori eradication therapy should be considered.
No applications for increased repeats will be authorised.

### Pantoprazole

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

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>2</td>
<td>..</td>
<td>31.05</td>
<td>32.20</td>
<td>Somac [NQ]</td>
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#### Pantoprazole 40 mg tablet: enteric, 30

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
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<tbody>
<tr>
<td>1</td>
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<td>11.54</td>
<td>12.69</td>
<td>APO-Pantoprazole [TX]</td>
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<td></td>
<td></td>
<td></td>
<td>- I-Pantoprazole [CR]</td>
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<td>- Panthron [ER]</td>
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<td>- Pantofast 40 [RZ]</td>
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<td>- Pantoprazole generic health [GQ]</td>
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<td>- Sozol [QA]</td>
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<td>- Topra 40 [DO]</td>
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#### Pantoprazole 20 mg tablet: enteric, 30 tablets

<table>
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<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
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<tr>
<td>1</td>
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<td>- Pantofast 20 [RZ]</td>
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<td>- Pantoprazole GA [GN]</td>
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<td>- Pantoprazole Sandoz [SZ]</td>
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<td>- Somac [NQ]</td>
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#### Pantoprazole 40 mg granules: enteric-coated, 30 sachets

<table>
<thead>
<tr>
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<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
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<tr>
<td>1</td>
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<td>31.05</td>
<td>32.20</td>
<td>Somac [NQ]</td>
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#### Pantoprazole 40 mg tablet: enteric, 30

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<td>- Salpraz [AF]</td>
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<td></td>
<td>- Sozol [QA]</td>
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<td></td>
<td></td>
<td>- Topra 40 [DO]</td>
</tr>
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</table>

### Rabeprazole

#### Rabeprazole

#### Rabeprazole sodium 10 mg tablet: enteric, 28

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<td>- Pariet [JC]</td>
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<td>- Chem mart Rabeprazole [CH]</td>
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<td>- Parzol 10 [ZP]</td>
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</tbody>
</table>
**ALIMENTARY TRACT AND METABOLISM**

**RABEPRAZOLE**

*Restricted benefit*

Initial treatment of peptic ulcer

**Note**

Helicobacter pylori eradication therapy should be considered. No applications for increased repeats will be authorised.

**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**

alginate sodium 500 mg/10 mL + calcium carbonate 160 mg/10 mL + sodium bicarbonate 267 mg/10 mL oral liquid, 500 mL

**SUCRALFATE**

sucralfate 1 g tablet, 120

**DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS**

**BELLADONNA AND DERIVATIVES, PLAIN**

*Belladonna alkaloids, tertiary amines*
### ATROPINE

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

<table>
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<th>Max.Qty Packs</th>
<th>No. of Rpts</th>
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<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</table>

**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.

### PROPULSIVES

**Propulsives**

### DOMPERIDONE

domperidone 10 mg tablet, 25

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### METOCLOPRAMIDE

**metoclopramide hydrochloride 10 mg tablet, 25**

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<td>Metoclopramide AN [EA]</td>
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<td>Metoclopramide RBX [RA]</td>
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**metoclopramide hydrochloride 10 mg tablet, 25**

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

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

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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.

**granisetron 3 mg/3 mL injection, 1 x 3 mL ampoule**

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
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<td>*Kytril [RO]</td>
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**GRANISETRON**

*Authority required (STREAMLINED)*

**4092**

Nausea and vomiting

**Clinical criteria:**

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

**granisetron 3 mg/3 mL injection, 1 x 3 mL ampoule**

<table>
<thead>
<tr>
<th>Max Qty</th>
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**GRANISETRON**

*Authority required (STREAMLINED)*

**4102**

Nausea and vomiting

**Clinical criteria:**

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

**granisetron 2 mg tablet, 5**

| Max Qty | Packs | No. of Rpts | Premium $ | DPMO $ | MRVSN $ | Brand Name and Manufacturer |
|---------|-------|-------------|-----------|--------|---------|----------------------------|----------------------------|
| 8873B   |       |             | 61.69     | 37.70  |         | Kytril [RO]                 |                             |
|         |       |             |           |        |         |                            |                            |

**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.

**granisetron 2 mg tablet, 1**

| Max Qty | Packs | No. of Rpts | Premium $ | DPMO $ | MRVSN $ | Brand Name and Manufacturer |
|---------|-------|-------------|-----------|--------|---------|----------------------------|----------------------------|
| 8728J   |       |             | *29.74*   | 30.89  |         | Kytril [RO]                 |                             |
|         |       |             |           |        |         |                            |                            |

**ONDANSETRON**

*Authority required (STREAMLINED)*

**3611**

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

**ondansetron 4 mg tablet, 10**

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<td><em>Onsetron 4 [ZP]</em></td>
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<td></td>
<td><em>Zitlofim 4 [DO]</em></td>
<td><em>Zofran [AS]</em></td>
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</tbody>
</table>

**ondansetron 4 mg/2 mL injection, 1 x 2 mL ampoule**

<table>
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<tr>
<th>Max Qty</th>
<th>Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMO $</th>
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<td><em>Ondansetron Alphapharm [AF]</em></td>
<td><em>Ondansetron Claris [AE]</em></td>
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<td></td>
<td><em>Ondansetron Kabi [PK]</em></td>
<td><em>Onsetron [ZP]</em></td>
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</tbody>
</table>

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

| Max Qty | Packs | No. of Rpts | Premium $ | DPMO $ | MRVSN $ | Brand Name and Manufacturer |
|---------|-------|-------------|-----------|--------|---------|----------------------------|----------------------------|
| 8233H   |       |             | 102.30    | 37.70  |         | Zofran syrup 50 mL [AS]     |                             |
|         |       |             |           |        |         |                            |                            |

**ondansetron 8 mg tablet, 10**

<table>
<thead>
<tr>
<th>Max Qty</th>
<th>Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMO $</th>
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<td></td>
<td></td>
<td><em>Ondansetron-DRLA [RZ]</em></td>
<td><em>Ondansetron SZ [HX]</em></td>
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<td></td>
<td><em>Ondaz [SZ]</em></td>
<td><em>Onsetron 8 [ZP]</em></td>
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<td><em>Zitlofim 8 [DO]</em></td>
<td><em>Zofran [AS]</em></td>
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**ondansetron 8 mg/4 mL injection, 1 x 4 mL ampoule**

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<th>Packs</th>
<th>No. of Rpts</th>
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<td><em>Ondansetron Claris [AE]</em></td>
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<td><em>Ondansetron Kabi [PK]</em></td>
<td><em>Onsetron [ZP]</em></td>
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</tbody>
</table>
### ONDANSETRON

**Restricted benefit**

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

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

#### ondansetron 4 mg tablet, 4

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
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<tbody>
<tr>
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<td>15.95</td>
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<td></td>
<td>* Ondansetron-DRLA [RZ]</td>
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<td></td>
<td></td>
<td></td>
<td>* Ondansetron SZ [HX]</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>* Zofran [AS]</td>
</tr>
</tbody>
</table>

#### ondansetron 4 mg/2 mL injection, 1 x 2 mL ampoule

<table>
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<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium</th>
<th>DPMO</th>
<th>MRVSN</th>
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<tbody>
<tr>
<td>1</td>
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<td></td>
<td>* Ondansetron-Claris [AE]</td>
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<td>* Ondansetron Kabi [PK]</td>
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<td></td>
<td>* Onsetron [ZP]</td>
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#### ondansetron 4 mg/5 mL oral liquid, 50 mL

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<td>102.30</td>
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#### ondansetron 8 mg tablet, 4

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<td></td>
<td>* Ondansetron-DRLA [RZ]</td>
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<td></td>
<td></td>
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<td></td>
<td></td>
<td>* Zofran [AS]</td>
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</table>

#### ondansetron 8 mg/4 mL injection, 1 x 4 mL ampoule

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
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<th>DPMO</th>
<th>MRVSN</th>
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<td>7.92</td>
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<td></td>
<td></td>
<td></td>
<td>* Ondansetron Kabi [PK]</td>
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<td></td>
<td></td>
<td></td>
<td>* Onsetron-Claris [AE]</td>
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<td></td>
<td></td>
<td></td>
<td>* Onsetron [ZP]</td>
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</tbody>
</table>

### ONDANSETRON

**Restricted benefit**

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

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

**Note**

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

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

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium</th>
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<tr>
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**ONDANSETRON Tablet (orally disintegrating) 8 mg, 4**

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<td></td>
<td></td>
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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.

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

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<tr>
<th>Max Qty Packs</th>
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### Ondansetron

**Ondansetron 8 mg wafer, 4**

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**Ondansetron 4 mg wafer, 10**

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**Ondansetron 8 mg wafer, 10**

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### Palonosetron

**Palonosetron 250 microgram/5 mL injection, 1 x 5 mL vial**

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### Tropisetron

**Tropisetron 5 mg/5 mL injection, 1 x 5 mL ampoule**

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### Aprepitant

**Aprepitant**

**Authority required (STREAMLINED)**

**ALIMENTARY TRACT AND METABOLISM**
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)

Nausea and vomiting

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

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

Authority required (STREAMLINED)

Nausea and vomiting

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

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.

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

### aprepitant 165 mg capsule, 1

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<td>138.13</td>
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### PROCHLORPERAZINE

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

**prochlorperazine maleate 25 mg suppository, 5**

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**prochlorperazine maleate 5 mg tablet, 25**

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<td></td>
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<td>* ProCalm [QA]</td>
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<td>* Stemzine [AV]</td>
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<td>1/2.70</td>
<td>10.89</td>
<td>9.34</td>
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**prochlorperazine mesylate 12.5 mg/mL injection, 10 x 1 mL ampoules**

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### 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.

### Prochlorperazine Maleate 25 mg Suppository, 5

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### Prochlorperazine Maleate 5 mg Tablet, 25

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<td>Stemzine [AV]</td>
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<tr>
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<td>2.70</td>
<td>10.89</td>
<td>9.34</td>
<td>Stemetil [SW]</td>
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</table>

### Prochlorperazine Mesylate 12.5 mg/mL Injection, 10 x 1 mL Ampoules

<table>
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### Promethazine

**Promethazine Hydrochloride 50 mg/2 mL Injection, 5 x 2 mL Ampoules**

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### Bile and Liver Therapy

**Bile Therapy**

**Bile Acid Preparations**

### Ursodeoxycholic Acid

**Authority required (STREAMLINED)**

1700
Primary biliary cirrhosis

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

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.

### 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**
Patients receiving palliative care

**Restricted benefit**
Terminal malignant neoplasia
### ALIMENTARY TRACT AND METABOLISM

#### Schedule of Pharmaceutical Benefits

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<tr>
<th>Brand Name and Manufacturer</th>
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<tr>
<td><em>Petrus Bisacodyl Suppositories [PP]</em></td>
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<td><strong>a</strong></td>
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</table>

### Bulk-forming laxatives

#### RHAMNUS FRANGULA + STERCULIA

**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

### LACTULOSE

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

**Restricted benefit**
Constipation in patients with malignant neoplasia

#### LACTULOSE Mixture 3.34 g per 5 mL, 500 mL, 1

### 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 be receiving palliative care.

**Restricted benefit**
Chronic constipation

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

**Restricted benefit**
Faecal impaction

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

### General

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

**Restricted benefit**
Chronic constipation

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

**Restricted benefit**
Faecal impaction

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

### 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.

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

**Restricted benefit**
Constipation

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

**Restricted benefit**
Constipation

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

**Restricted benefit**
Constipation

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

**Restricted benefit**
Chronic constipation

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

**Restricted benefit**
Faecal impaction

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

### Enemas

**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

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

<table>
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Sorbitol + Citrate + Lauryl Sulfoacetate SODIUM

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

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

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

Restricted benefit
Patients receiving palliative care

Restricted benefit
Terminal malignant neoplasia

Restricted benefit
Anorectal congenital abnormalities

Megacolon

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

<table>
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Other drugs for constipation

GLYCEROL

Restricted benefit
Paraplelgic 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

Megacolon

glycerol 1.4 g suppository, 12

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glycerol 2.8 g suppository, 12

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<td>2557N</td>
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<td></td>
<td>Petrus Pharmaceuticals Pty Ltd [PP]</td>
</tr>
</tbody>
</table>
General

glycerol 700 mg suppository, 12

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>Petrus Pharmaceuticals Pty Ltd [PP]</td>
</tr>
</tbody>
</table>

ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATORY/ANTIINFECTIVE AGENTS

INTESTINAL ANTIINFECTIVES

Antibiotics

NYSTATIN

nystatin 500 000 international units capsule, 50

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nilstat [QA]</td>
</tr>
</tbody>
</table>

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

Rifaximin 550 mg tablet, 56

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Xifaxan [NE]</td>
</tr>
</tbody>
</table>

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.

Vancomycin 125 mg capsule, 20

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vancocin [AS]</td>
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</tbody>
</table>

Vancomycin 250 mg capsule, 20

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vancocin [AS]</td>
</tr>
</tbody>
</table>

ELECTROLYTES WITH CARBOHYDRATES

Oral rehydration salt formulations
**ALIMENTARY TRACT AND METABOLISM**

### 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.

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Max.Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
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<tr>
<td><em>O.R.S. [AS]</em></td>
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<td>13.25</td>
<td>14.40</td>
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<tr>
<td><em>Repalyte New Formulation [SW]</em></td>
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<td>13.25</td>
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<tr>
<td><em>restore O.R.S. [GN]</em></td>
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<td>..</td>
<td>13.25</td>
<td>14.40</td>
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### ANTIPROPULSIVES

#### DIPHENOXYLATE + ATROPINE SULFATE

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

<table>
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<tr>
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<tr>
<td><em>Lofenoxal [IA]</em></td>
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<td>8.81</td>
<td>9.96</td>
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<td><em>Lomotil [IV]</em></td>
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<td>10.54</td>
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### LOPERAMIDE

loperamide hydrochloride 2 mg capsule, 12

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<th>DPMQ $</th>
<th>MRVSN $</th>
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<td>9.22</td>
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### INTESTINAL ANTIINFLAMMATORY AGENTS

#### Corticosteroids acting locally

### BUDESONIDE

**Note**

Continuing Therapy Only:

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

budesonide 2 mg/application enema, 2 x 14 applications aerosol cans

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Max.Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
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<tbody>
<tr>
<td><em>Budenofalk [OA]</em></td>
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<td>3</td>
<td>211.65</td>
<td>37.70</td>
<td></td>
</tr>
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</table>

### HYDROCORTISONE ACETATE

**Restricted benefit**

Proctitis

**Restricted benefit**

Ulcerative colitis

**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.

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

<table>
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<th>DPMQ $</th>
<th>MRVSN $</th>
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<tbody>
<tr>
<td><em>Colifoam [HM]</em></td>
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<td>3</td>
<td>*40.78</td>
<td>37.70</td>
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</tr>
</tbody>
</table>

### PREDNISOLONE SODIUM PHOSPHATE

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

<table>
<thead>
<tr>
<th>1920C</th>
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<th>No. of Rpts</th>
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<th>DPMO $</th>
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</table>

**PREDNISOLONE SODIUM PHOSPHATE**

**Restricted benefit**
Proctitis

**Restricted benefit**
Ulcerative colitis

**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.

prednisolone (as sodium phosphate) 5 mg suppository, 10

<table>
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</table>

**Aminosalicylic acid and similar agents**

**BALSALAZIDE**

**Authority required (STREAMLINED)**

| 4824 | Ulcerative colitis |

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

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

**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.

balsalazide sodium 750 mg capsule, 180

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<th>Brand Name and Manufacturer</th>
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<tr>
<td></td>
<td>1</td>
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<td>125.19</td>
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<td>Colazide [PK]</td>
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</table>

**MESALAZINE**

**Authority required (STREAMLINED)**

| 4824 | Ulcerative colitis |

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

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

**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.

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

<table>
<thead>
<tr>
<th>8599N</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMO $</th>
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<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td></td>
<td>1</td>
<td>5</td>
<td>..</td>
<td>279.97</td>
<td>37.70</td>
<td>Salofalk [OA]</td>
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</table>

mesalazine 1.2 g tablet: modified release, 60 tablets

<table>
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<tr>
<th>9353G</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMO $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
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<tbody>
<tr>
<td></td>
<td>1</td>
<td>5</td>
<td>..</td>
<td>221.33</td>
<td>37.70</td>
<td>Mezavant [ZI]</td>
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</tbody>
</table>

mesalazine 1.5 g granules, 60 x 1.5 g sachets

<table>
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<tr>
<th>9206M</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMO $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1</td>
<td>5</td>
<td>..</td>
<td>245.26</td>
<td>37.70</td>
<td>Salofalk [OA]</td>
</tr>
<tr>
<td>Mesalazine 3 g granules, 30 sachets</td>
<td>Max Qty Packs</td>
<td>No. of Rpts</td>
<td>Premium $</td>
<td>DPMQ $</td>
<td>MRVSN $</td>
<td>Brand Name and Manufacturer</td>
</tr>
<tr>
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<td>---------</td>
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<td>5</td>
<td>..</td>
<td>245.26</td>
<td>37.70</td>
<td>Salofalk [OA]</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Mesalazine 4 g granules: modified release, 30 sachets</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
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<td>5</td>
<td>..</td>
<td>312.64</td>
<td>37.70</td>
<td>Pentasa [FP]</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Mesalazine 500 mg granules, 100 x 500 mg sachets</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>8598M</td>
<td>2</td>
<td>5</td>
<td>..</td>
<td>*297.78</td>
<td>37.70</td>
<td>Salofalk [OA]</td>
</tr>
</tbody>
</table>

**MESALAZINE**

**Authority required (STREAMLINED)**

**4873**

Ulcerative colitis

**Clinical criteria:**

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

Patient must be intolerant to sulfasalazine.

**Authority required (STREAMLINED)**

**4896**

Crohn disease

**Clinical criteria:**

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

Patient must be intolerant to 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 initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

<table>
<thead>
<tr>
<th>Mesalazine 1 g granules: modified release, 120 x 1 g sachets</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
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<td>5</td>
<td>..</td>
<td>331.01</td>
<td>37.70</td>
<td>Pentasa [FP]</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Mesalazine 1 g tablet: modified release, 60 tablets</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>3413P</td>
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<td>5</td>
<td>..</td>
<td>*331.02</td>
<td>37.70</td>
<td>Pentasa [FP]</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Mesalazine 2 g granules: modified release, 60 x 2 g sachets</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
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<td>312.64</td>
<td>37.70</td>
<td>Pentasa [FP]</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Mesalazine 250 mg tablet: enteric, 100 tablets</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tr>
<td>1611T</td>
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<td>93.77</td>
<td>37.70</td>
<td>Mesasal [AS]</td>
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</table>

<table>
<thead>
<tr>
<th>Mesalazine 500 mg tablet: enteric, 100 tablets</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<td>..</td>
<td>*297.78</td>
<td>37.70</td>
<td>Salofalk [OA]</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Mesalazine 500 mg tablet: modified release, 100 tablets</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<td>..</td>
<td>*297.78</td>
<td>37.70</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

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

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

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

**Mesalazine 1 g suppository, 30**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tr>
<td>5461K</td>
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<td>136.73</td>
<td>37.70</td>
<td>Salofalk [OA]</td>
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**Mesalazine 1 g suppository, 30**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
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<th>Brand Name and Manufacturer</th>
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<td>37.70</td>
<td>Pentasa [FP]</td>
</tr>
</tbody>
</table>

**Mesalazine**

- Authority required (STREAMLINED)
- 4888
- Acute episode of mild to moderate ulcerative colitis

**Note**

Not for the treatment of Crohn disease

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

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

**Continuing Therapy Only:**

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

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

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>8753Q</td>
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<td>1</td>
<td>...</td>
<td>*336.56</td>
<td>Pentasa [FP]</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
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<td>1</td>
<td>...</td>
<td>*336.56</td>
<td>Salofalk [OA]</td>
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</table>

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

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
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<td>...</td>
<td>*336.56</td>
<td>Salofalk [OA]</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
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<th>Brand Name and Manufacturer</th>
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<td>*446.24</td>
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**Olsalazine sodium 250 mg capsule, 100**

<table>
<thead>
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<th>Max Qty Packs</th>
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<th>Premium $</th>
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<td>5</td>
<td>...</td>
<td>61.75</td>
<td>Dipentum [IX]</td>
</tr>
</tbody>
</table>

**Olsalazine sodium 500 mg tablet, 100**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>8086N</td>
<td>1</td>
<td>5</td>
<td>...</td>
<td>103.63</td>
<td>Dipentum [IX]</td>
</tr>
</tbody>
</table>

**Olsalazine**

- Authority required (STREAMLINED)
- 4824
- Ulcerative colitis

**Clinical criteria:**

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

Patient must be intolerant to sulfasalazine.

**Note**

Not for the treatment of Crohn disease

**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.
### 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.

### SULFASALAZINE Table 500 mg (enteric coated), 100

<table>
<thead>
<tr>
<th></th>
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<th>DPMO $</th>
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<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>Sulfasalazine 500 mg tablet, 100</td>
<td>2096H</td>
<td>5</td>
<td>*54.60</td>
<td>37.70</td>
<td>*Pyralin EN [FZ]</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>2.48</td>
<td>57.08</td>
<td>*Salazopyrin-EN [PF]</td>
<td></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 increase in the maximum quantity or number of units may be authorised.

### DIGESTIVES, INCL. ENZYMES

**Enzyme preparations**

### PANCREATIC EXTRACT

**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.

### 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.
pancreatic extract 10 000 international units capsule: modified release, 100 capsules

9226N

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
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<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>5</td>
<td>21</td>
<td>..</td>
<td>*184.01</td>
<td>37.70</td>
<td>Creon 10,000 [GO]</td>
</tr>
</tbody>
</table>

pancreatic extract 25 000 international units capsule: modified release, 100 capsules

9227P

<table>
<thead>
<tr>
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<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>2</td>
<td>21</td>
<td>..</td>
<td>*148.08</td>
<td>37.70</td>
<td>Creon 25,000 [GO]</td>
</tr>
</tbody>
</table>

pancreatic extract 40 000 international units capsule: modified release, 100 capsules

9413K

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<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tr>
<td>2</td>
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<td>..</td>
<td>*230.30</td>
<td>37.70</td>
<td>Creon 40,000 [GO]</td>
</tr>
</tbody>
</table>

pancreatic extract 5000 international units/100 mg granules: enteric-coated, 20 g

5454C

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<tr>
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<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>3</td>
<td>21</td>
<td>..</td>
<td>*142.12</td>
<td>37.70</td>
<td>Creon Micro [GO]</td>
</tr>
</tbody>
</table>

### PANCRELIPASE

**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.

pancrelipase 25 000 units capsule, 100

8366H

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>10</td>
<td>..</td>
<td>*138.24</td>
<td>37.70</td>
<td>Panzytrat 25000 [TM]</td>
</tr>
</tbody>
</table>

### PANCRELIPASE

**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.

pancrelipase 25 000 units capsule, 100

9229R

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>21</td>
<td>..</td>
<td>*138.24</td>
<td>37.70</td>
<td>Panzytrat 25000 [TM]</td>
</tr>
</tbody>
</table>

### DRUGS USED IN DIABETES

### INSULINS AND ANALOGUES

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

### INSULIN ASPART

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

8571D

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>5</td>
<td>2</td>
<td>..</td>
<td>*159.61</td>
<td>37.70</td>
<td>NovoRapid [NO]</td>
</tr>
</tbody>
</table>

inguin aspart 100 international units/mL injection, 5 x 3 mL cartridges

8435Y

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>5</td>
<td>1</td>
<td>..</td>
<td>*264.56</td>
<td>37.70</td>
<td>NovoRapid FlexPen [NF]</td>
</tr>
</tbody>
</table>

### INSULIN GLULISINE

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

9224L

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>5</td>
<td>2</td>
<td>..</td>
<td>*159.61</td>
<td>37.70</td>
<td>Apidra [SW]</td>
</tr>
</tbody>
</table>

ingulin glulisine 100 international units/mL injection, 5 x 3 mL cartridges

1921D

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>5</td>
<td>1</td>
<td>..</td>
<td>*264.56</td>
<td>37.70</td>
<td>Apidra SoloStar [SW]</td>
</tr>
</tbody>
</table>
### INSULIN LISPRO

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

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>8084L</td>
<td>5</td>
<td>2</td>
<td>..</td>
<td>*159.61</td>
<td>Humalog [LY]</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>8212F</td>
<td>5</td>
<td>1</td>
<td>..</td>
<td>*264.56</td>
<td>Humalog [LY] Humalog KwikPen [KP]</td>
</tr>
</tbody>
</table>

### INSULIN NEUTRAL BOVINE

**Authority required**

Diabetes mellitus  

**Clinical criteria:**

Patient must be intolerant to human insulin.

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

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1713E</td>
<td>5</td>
<td>2</td>
<td>..</td>
<td>*401.06</td>
<td>Hypurin Neutral [AS]</td>
</tr>
</tbody>
</table>

### INSULIN NEUTRAL HUMAN

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

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1531N</td>
<td>5</td>
<td>2</td>
<td>..</td>
<td>*134.16</td>
<td>Actrapid [NO] Humulin R [LY]</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1762R</td>
<td>5</td>
<td>1</td>
<td>..</td>
<td>*224.66</td>
<td>Actrapid Penfill 3 mL [NO] Humulin R [LY]</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.

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

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1711C</td>
<td>5</td>
<td>2</td>
<td>..</td>
<td>*401.06</td>
<td>Hypurin Isophane [AS]</td>
</tr>
</tbody>
</table>

### INSULIN ISOPHANE HUMAN

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

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1533Q</td>
<td>5</td>
<td>2</td>
<td>..</td>
<td>*134.16</td>
<td>Humulin NPH [LY] Protaphane [NO]</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1761Q</td>
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<td>1</td>
<td>..</td>
<td>*224.66</td>
<td>Humulin NPH [LY] Protaphane InnoLet [NI] Protaphane Penfill 3 mL [NO]</td>
</tr>
</tbody>
</table>

### INSULINS AND ANALOGUES FOR INJECTION, INTERMEDIATE- OR LONG-ACTING COMBINED WITH FAST-ACTING

### INSULIN ASPART + INSULIN ASPART PROTAMINE

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

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>8609D</td>
<td>5</td>
<td>1</td>
<td>..</td>
<td>*264.56</td>
<td>NovoMix 30 FlexPen [NF] NovoMix 30 Penfill 3 mL [NO]</td>
</tr>
</tbody>
</table>

### INSULIN ISOPHANE HUMAN + INSULIN NEUTRAL HUMAN

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

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1763T</td>
<td>5</td>
<td>1</td>
<td>..</td>
<td>*224.66</td>
<td>Humulin 30/70 [LY] Mixtard 30/70 Penfill 3 mL [NO] Mixtard 30/70 InnoLet [NI]</td>
</tr>
</tbody>
</table>

Schedule of Pharmaceutical Benefits 59
insulin neutral human 30 international units/mL + insulin isophane human 70 international units/mL injection, 1 x 10 mL vial

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
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<td>1426C</td>
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<td>2</td>
<td>..</td>
<td>134.16</td>
<td>37.70 Humulin 30/70 [LY]</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
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<tbody>
<tr>
<td>2062M</td>
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<td>..</td>
<td>224.66</td>
<td>37.70 Mixtard 50/50 Penfill 3 mL [NO]</td>
</tr>
</tbody>
</table>

**INSULIN LISPRO + INSULIN LISPRO PROTAMINE**

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

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<td>8390N</td>
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<td>..</td>
<td>264.56</td>
<td>37.70 Humalog Mix25 [LY]</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
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<td>1</td>
<td>..</td>
<td>264.56</td>
<td>37.70 Humalog Mix50 [LY]</td>
</tr>
</tbody>
</table>

**INSULIN DETEMIR**

Restricted benefit
Type 1 diabetes

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

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>9040T</td>
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<td>1</td>
<td>..</td>
<td>433.06</td>
<td>37.70 Levemir FlexPen [NF]</td>
</tr>
</tbody>
</table>

**INSULIN GLARGINE**

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

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>9039R</td>
<td>5</td>
<td>1</td>
<td>..</td>
<td>433.06</td>
<td>37.70 Lantus [SW]</td>
</tr>
</tbody>
</table>

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

**Biguanides**

**METFORMIN**

metformin hydrochloride 1 g tablet, 90

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>8607B</td>
<td>1</td>
<td>5</td>
<td>..</td>
<td>12.77</td>
<td>13.92 * APO-Metformin 1000 [TX]</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>3439B</td>
<td>1</td>
<td>5</td>
<td>..</td>
<td>12.29</td>
<td>13.44 * APO-Metformin XR 1000 [TX]</td>
</tr>
</tbody>
</table>

**metformin hydrochloride 500 mg tablet, 100**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>2430X</td>
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<td>5</td>
<td>..</td>
<td>10.21</td>
<td>11.36 * APO-Metformin 500 [TX]</td>
</tr>
</tbody>
</table>

ALIMENTARY TRACT AND METABOLISM
### ALIMENTARY TRACT AND METABOLISM

#### Schedule of Pharmaceutical Benefits

<table>
<thead>
<tr>
<th>Metformin hydrochloride 500 mg tablet: modified release, 120 tablets</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>943SN</strong></td>
</tr>
<tr>
<td>1</td>
</tr>
<tr>
<td>1</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Metformin hydrochloride 850 mg tablet, 60</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1801T</strong></td>
</tr>
<tr>
<td>1</td>
</tr>
<tr>
<td>1</td>
</tr>
</tbody>
</table>

### Sulfonylureas

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

<table>
<thead>
<tr>
<th>Glibenclamide 5 mg tablet, 100</th>
</tr>
</thead>
<tbody>
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- **GLICLAZIDE**
  - **Caution**
  - Sulfonylureas may cause hypoglycaemia, particularly in the elderly.

<table>
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### GLIMEPIRIDE

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

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**GLIPIZIDE**

Caution
Sulfonylureas may cause hypoglycaemia, particularly in the elderly.

**glipizide 5 mg tablet, 100**

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**Combinations of oral blood glucose lowering drugs**

**ALOGLIPTIN + METFORMIN**

*Authority required (STREAMLINED)*

4423
Diabetes mellitus type 2

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

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

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

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

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a 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.
Linagliptin 12.5 mg + metformin hydrochloride 1 g tablet, 56

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

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

**LINAGLIPTIN + METFORMIN**

**Authority required (STREAMLINED)**

4423

Diabetes mellitus type 2

Clinical criteria:

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

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

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

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

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

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

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

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

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

**Authority required (STREAMLINED)**

4448

Diabetes mellitus type 2

Treatment Phase: Continuing

Clinical criteria:

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

Note

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

Linagliptin 2.5 mg + metformin hydrochloride 1 g tablet, 60

Linagliptin 2.5 mg + metformin hydrochloride 500 mg tablet, 60

Linagliptin 2.5 mg + metformin hydrochloride 850 mg tablet, 60

**METFORMIN + GLIBENCLAMIDE**

Caution

Sulfonylureas may cause hypoglycaemia, particularly in the elderly.

Metformin hydrochloride 250 mg + glibenclamide 1.25 mg tablet, 90
metformin hydrochloride 500 mg + glibenclamide 2.5 mg tablet, 90

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metformin hydrochloride 500 mg + glibenclamide 5 mg tablet, 90

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**ROSIGLITAZONE + METFORMIN**

**Authority required**

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

**Note**

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

rosiglitazone 2 mg + metformin hydrochloride 1 g tablet, 56

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rosiglitazone 2 mg + metformin hydrochloride 500 mg tablet, 56

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rosiglitazone 4 mg + metformin hydrochloride 1 g tablet, 56

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rosiglitazone 4 mg + metformin hydrochloride 500 mg tablet, 56

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**SAXAGLIPTIN + METFORMIN**

**Authority required (STREAMLINED)**

**Clinical criteria:**
- Diabetes mellitus type 2
- 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.

**Note**

4423

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

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

**Authority required (STREAMLINED)**

**4451**

Diabetes mellitus type 2

**Treatment Phase: Continuing**

**Clinical criteria:**

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

**Note**

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

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

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

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

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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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**sitagliptin 100 mg + metformin hydrochloride 1 g tablet: modified release, 28**

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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 who has 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.
ACARBOSE

acarbose 100 mg tablet, 90

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acarbose 50 mg tablet, 90

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Thiazolidinediones

PIOGLITAZONE

Authority required (STREAMLINED)

4383
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 was initiated.
The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

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

Authority required (STREAMLINED)

4388
Diabetes mellitus type 2
Clinical criteria:
The treatment must be in combination with insulin, AND
Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated; OR
Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated.
The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was 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 of 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

#### ROSIGLITAZONE

**Authority required**

Diabetes mellitus type 2

**Clinical criteria:**

The treatment must be in combination with metformin; **OR**

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

Patient must have a contraindication to a combination of metformin and a sulfonylurea; **OR**

Patient must not have tolerated a combination of metformin and a sulfonylurea, **AND**

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

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

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#### pioglitazone 15 mg tablet, 28

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### ALIMENTARY TRACT AND METABOLISM
The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated. The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

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

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

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

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

**Note**

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

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

### ALOGLIPTIN

**Authority required (STREAMLINED)**

**4349**

Diabetes mellitus type 2

**Clinical criteria:**

The treatment must be in combination with metformin; OR

The treatment must be in combination with a sulfonylurea, AND

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

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

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

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

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

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

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

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

### alogliptin 12.5 mg tablet, 28

**2933J**

Max Qty Packs  | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer
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### alogliptin 25 mg tablet, 28

**2986E**

Max Qty Packs  | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer
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### alogliptin 6.25 mg tablet, 28

**2944Y**

Max Qty Packs  | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer
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### LINAGLIPTIN

**Authority required (STREAMLINED)**

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Schedule of Pharmaceutical Benefits
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 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.

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.

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SAXAGLIPTIN

Authority required (STREAMLINED)

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 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.

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.

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### SITAGLIPTIN

**Authority required (STREAMLINED)**

**4519**

Diabetes mellitus type 2

**Clinical criteria:**

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

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

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

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

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

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

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

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

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

**Note**

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

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### VILDAGLIPTIN

**Authority required (STREAMLINED)**

**4467**

Diabetes mellitus type 2

**Clinical criteria:**

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

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

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

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

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

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

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

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

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

**Note**

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

### 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

- 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.

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

- A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or
- 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.

This drug 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.

### DAPAGLIFLOZIN

**Authority required (STREAMLINED)**

*4844*

Diabetes mellitus type 2

**Clinical criteria:**

The treatment must be in combination with metformin; OR

The treatment must be in combination with a sulfonylurea, AND

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

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

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

The HbA1c must be no more than 4 months old at the time treatment with a gliptin was initiated.

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

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

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

**Authority required (STREAMLINED)**

### EMPAGLIFLOZIN

**Diabetes mellitus type 2**

**Clinical criteria:**

The treatment must be in combination with insulin, AND

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

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

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient’s medical records.

The HbA1c 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 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.

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

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**Dapagliflozin**

**Empagliflozin**

**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 dipeptidyl peptidase 4 inhibitor (gliptin) or a glucagon-like peptide-1 is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a dipeptidyl peptidase 4 inhibitor (gliptin) or 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:**

Further information can be found in the Explanatory Notes for Nurse Practitioners.
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.

This drug 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.

**Empagliflozin 10 mg tablet, 30**

<table>
<thead>
<tr>
<th>Max. Qty/Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
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<td>10206E</td>
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**Empagliflozin 25 mg tablet, 30**

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<td>...</td>
<td>62.37</td>
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### EXENATIDE

**Authority required (STREAMLINED)**

**4856**

Diabetes mellitus type 2

**Clinical criteria:**

The treatment must be in combination with metformin; OR

The treatment must be in combination with a sulfonylurea, AND

Patient must have a contraindication to a combination of metformin and a sulfonylurea; OR

Patient must not have tolerated a combination of metformin and a sulfonylurea, AND

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

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

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

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

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

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

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

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

**Authority required (STREAMLINED)**

**4857**

Diabetes mellitus type 2

**Clinical criteria:**

The treatment must be in combination with metformin, AND

The treatment must be in combination with a sulfonylurea, AND

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

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

**Vitamin D and analogues**

##### CALCITRIOL

- **Authority required (STREAMLINED)**
- **1165** Hypocalcaemia due to renal disease
- **Authority required (STREAMLINED)**
- **1166** Hypoparathyroidism
- **Authority required (STREAMLINED)**
- **1167** Hypophosphataemic rickets
- **Authority required (STREAMLINED)**
- **1467** Vitamin D-resistant rickets
- **Authority required (STREAMLINED)**
- **2636** Treatment for established osteoporosis in patients with fracture due to minimal trauma. The fracture must have been demonstrated radiologically and the year of plain x-ray or CT-scan or MRI scan must be documented in the patient's medical records when treatment is initiated.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

**calcitriol 0.25 microgram capsule, 100**

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<td>Calcitriol-GA [UA]</td>
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<td>GenRx Calcitriol [GX]</td>
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#### THIAMINE

- **Authority required (STREAMLINED)**
- **2384** Prophylaxis of thiamine deficiency in an Aboriginal or a Torres Strait Islander person

**thiamine hydrochloride 100 mg tablet, 100**

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#### MINERAL SUPPLEMENTS

#### CALCIUM

**Calcium**

- **Authority required (STREAMLINED)**
- **4586** Hyperphosphataemia

**Clinical criteria:**

The condition must be associated with chronic renal failure.
CALCIUM Tablet (chewable) 500 mg (as carbonate), 60

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<td>29.24</td>
<td>30.39</td>
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<td>* Cal-Sup [IA]</td>
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CALCIUM Tablet 600 mg (as carbonate), 240

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<td>22.54</td>
<td>23.69</td>
<td>Calci-Tab 600 [AE]</td>
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POTASSIUM

POTASSIUM CHLORIDE

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

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

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<td>13.22</td>
<td>14.37</td>
<td>* Duro-K [NM]</td>
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<td></td>
<td>2.94</td>
<td>16.16</td>
<td>* Slow-K [NV]</td>
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potassium chloride 600 mg (8 mmol potassium) tablet: modified release, 200 tablets

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<td>13.21</td>
<td>14.36</td>
<td>* Span-K [AS]</td>
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POTASSIUM CHLORIDE + POTASSIUM BICARBONATE + POTASSIUM CARBONATE

potassium chloride 595 mg + potassium bicarbonate 384 mg + potassium carbonate 152 mg (total potassium 14 mmol) tablet: effervescent, 60

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OTHER MINERAL SUPPLEMENTS

Magnesium

MAGNESIUM ASPARTATE DIHYDRATE

Authority required
Hypomagnesaemia in an Aboriginal or a Torres Strait Islander person

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

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

<table>
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ANABOLIC AGENTS FOR SYSTEMIC USE

ANABOLIC STEROIDS

Estren derivatives

NANDROLONE DECANOATE

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

Authority required
Monotherapy for osteoporosis, where other treatment is not tolerated and where specialist advice confirms that this is the only suitable treatment 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

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.
nandrolone decanoate 50 mg/mL injection, 1 x 1 mL syringe

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<td>Deca-Durabolin [AS]</td>
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**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.

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

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**Sapropterin**

**Authority required**

Hyperphenylalaninaemia

**Clinical criteria:**

Patient must have hyperphenylalaninaemia (HPA) due to tetrahydrobiopterin (BH4) deficiency, **AND**

Patient must have previously been issued with an authority prescription for this drug; **OR**

Patient must have accessed non-PBS-subsidised treatment prior to 1 May 2014.

Patient must have documented tetrahydrobiopterin (BH4) deficiency using tests for BH4 loading and/or urine pterin metabolites, blood spot dihydrosydropteridine 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).

Prescribing information (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 dihydrochloride 100 mg tablet: soluble, 30 tablets

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<th>Max Qty Packs</th>
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<td>*5306.74</td>
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**Sapropterin**

**Authority required**

Hyperphenylalaninaemia

**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 dihydrosydropteridine 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.

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

Prescribing information (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 dihydrochloride 100 mg tablet: soluble, 30 tablets

<table>
<thead>
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### BLOOD AND BLOOD FORMING ORGANS

### ANTITHROMBOTIC AGENTS

#### Vitamin K antagonists

### WARFARIN

**Caution**

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

#### warfarin sodium 1 mg tablet, 50

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<td>Marevan [FM]</td>
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#### warfarin sodium 2 mg tablet, 50

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#### warfarin sodium 3 mg tablet, 50

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#### warfarin sodium 5 mg tablet, 50

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#### Heparin group

### DALTEPARIN SODIUM

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

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#### dalteparin sodium 12 500 anti-Xa international units/0.5 mL injection, 10 x 0.5 mL syringes

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

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#### dalteparin sodium 5000 anti-Xa international units/0.2 mL injection, 10 x 0.2 mL syringes

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#### dalteparin sodium 7500 anti-Xa international units/0.75 mL injection, 10 x 0.75 mL syringes

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<td></td>
<td>Fragmin [PF]</td>
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</tbody>
</table>

### DALTEPARIN SODIUM

**Restricted benefit**

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

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No of Rpts</th>
<th>Premium $</th>
<th>DPMO $</th>
<th>MRVSN $</th>
</tr>
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<tbody>
<tr>
<td>2</td>
<td>3</td>
<td>..</td>
<td>175.90</td>
<td>37.70</td>
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</tbody>
</table>


dalteparin sodium 12 500 anti-Xa international units/0.5 mL injection, 10 x 0.5 mL syringes

<table>
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<tr>
<th>Max Qty Packs</th>
<th>No of Rpts</th>
<th>Premium $</th>
<th>DPMO $</th>
<th>MRVSN $</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
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<td>..</td>
<td>241.62</td>
<td>37.70</td>
</tr>
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</table>


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

<table>
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<th>Max Qty Packs</th>
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<th>Premium $</th>
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<th>MRVSN $</th>
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<tbody>
<tr>
<td>2</td>
<td>3</td>
<td>..</td>
<td>105.08</td>
<td>37.70</td>
</tr>
</tbody>
</table>


dalteparin sodium 5000 anti-Xa international units/0.2 mL injection, 10 x 0.2 mL syringes

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No of Rpts</th>
<th>Premium $</th>
<th>DPMO $</th>
<th>MRVSN $</th>
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<tbody>
<tr>
<td>2</td>
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<td>..</td>
<td>109.22</td>
<td>37.70</td>
</tr>
</tbody>
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dalteparin sodium 7500 anti-Xa international units/0.75 mL injection, 10 x 0.75 mL syringes

<table>
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<th>Max Qty Packs</th>
<th>No of Rpts</th>
<th>Premium $</th>
<th>DPMO $</th>
<th>MRVSN $</th>
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</thead>
<tbody>
<tr>
<td>2</td>
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<td>..</td>
<td>130.68</td>
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</table>

- **DALTEPARIN SODIUM**

  Restricted benefit
  Symptomatic venous thromboembolism
  Treatment Phase: Management
  Clinical criteria:
  Patient must have a solid tumour(s).

  Note
  No applications for increased maximum quantities will be authorised.

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

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No of Rpts</th>
<th>Premium $</th>
<th>DPMO $</th>
<th>MRVSN $</th>
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</thead>
<tbody>
<tr>
<td>3</td>
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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

<table>
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<th>MRVSN $</th>
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<tbody>
<tr>
<td>3</td>
<td>5</td>
<td>..</td>
<td>493.93</td>
<td>37.70</td>
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</table>

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

<table>
<thead>
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<th>Max Qty Packs</th>
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<th>Premium $</th>
<th>DPMO $</th>
<th>MRVSN $</th>
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<tbody>
<tr>
<td>3</td>
<td>5</td>
<td>..</td>
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</table>

dalteparin sodium 12 500 anti-Xa international units/0.5 mL injection, 10 x 0.5 mL syringes

<table>
<thead>
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<th>Premium $</th>
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<td>350.05</td>
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dalteparin sodium 7500 anti-Xa international units/0.75 mL injection, 10 x 0.75 mL syringes

<table>
<thead>
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<th>Premium $</th>
<th>DPMO $</th>
<th>MRVSN $</th>
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<tbody>
<tr>
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<td>192.64</td>
<td>37.70</td>
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</table>

- **ENOXAPARIN SODIUM**

enoxaparin sodium 100 mg/mL injection, 10 x 1 mL syringes

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No of Rpts</th>
<th>Premium $</th>
<th>DPMO $</th>
<th>MRVSN $</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>1</td>
<td>..</td>
<td>109.42</td>
<td>37.70</td>
</tr>
</tbody>
</table>

enoxaparin sodium 20 mg/0.2 mL injection, 10 x 0.2 mL syringes

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No of Rpts</th>
<th>Premium $</th>
<th>DPMO $</th>
<th>MRVSN $</th>
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</thead>
<tbody>
<tr>
<td>2</td>
<td>..</td>
<td>..</td>
<td>105.08</td>
<td>37.70</td>
</tr>
</tbody>
</table>

enoxaparin sodium 40 mg/0.4 mL injection, 10 x 0.4 mL ampoules

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No of Rpts</th>
<th>Premium $</th>
<th>DPMO $</th>
<th>MRVSN $</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>..</td>
<td>..</td>
<td>109.22</td>
<td>37.70</td>
</tr>
</tbody>
</table>
### Enoxaparin Sodium 40 mg/0.4 mL Injection, 10 x 0.4 mL Syringes

<table>
<thead>
<tr>
<th>Code</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>8510X</td>
<td>2</td>
<td>..</td>
<td>..</td>
<td>*109.22</td>
<td>37.70</td>
<td>Clexane [SW]</td>
</tr>
</tbody>
</table>

### Enoxaparin Sodium 60 mg/0.6 mL Injection, 10 x 0.6 mL Syringes

<table>
<thead>
<tr>
<th>Code</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tr>
<td>8262W</td>
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<td>1</td>
<td>..</td>
<td>80.02</td>
<td>37.70</td>
<td>Clexane [SW]</td>
</tr>
</tbody>
</table>

### Enoxaparin Sodium 80 mg/0.8 mL Injection, 10 x 0.8 mL Syringes

<table>
<thead>
<tr>
<th>Code</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>8263X</td>
<td>1</td>
<td>1</td>
<td>..</td>
<td>91.04</td>
<td>37.70</td>
<td>Clexane [SW]</td>
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</tbody>
</table>

#### Enoxaparin Sodium

- **Restricted benefit**
- **Haemodialysis**

### Enoxaparin Sodium 100 mg/mL Injection, 10 x 1 mL Syringes

<table>
<thead>
<tr>
<th>Code</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>5435C</td>
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<td>3</td>
<td>..</td>
<td>*211.42</td>
<td>37.70</td>
<td>Clexane [SW]</td>
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</tbody>
</table>

### Enoxaparin Sodium 20 mg/0.2 mL Injection, 10 x 0.2 mL Syringes

<table>
<thead>
<tr>
<th>Code</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>8716R</td>
<td>2</td>
<td>3</td>
<td>..</td>
<td>*105.08</td>
<td>37.70</td>
<td>Clexane [SW]</td>
</tr>
</tbody>
</table>

### Enoxaparin Sodium 40 mg/0.4 mL Injection, 10 x 0.4 mL Syringes

<table>
<thead>
<tr>
<th>Code</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>8639Q</td>
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<td>..</td>
<td>*109.22</td>
<td>37.70</td>
<td>Clexane [SW]</td>
</tr>
</tbody>
</table>

### Enoxaparin Sodium 60 mg/0.6 mL Injection, 10 x 0.6 mL Syringes

<table>
<thead>
<tr>
<th>Code</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
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<td>8640R</td>
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<td>Clexane [SW]</td>
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</tbody>
</table>

### Enoxaparin Sodium 80 mg/0.8 mL Injection, 10 x 0.8 mL Syringes

<table>
<thead>
<tr>
<th>Code</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>5434B</td>
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<td>..</td>
<td>*175.32</td>
<td>37.70</td>
<td>Clexane [SW]</td>
</tr>
</tbody>
</table>

#### Enoxaparin Sodium

- **Restricted benefit**
- **Haemodialysis**

### Heparin Sodium

- **heparin sodium 35 000 international units/35 mL injection, 1 x 35 mL vial**
  - Code 1076P: Max Qty Packs = 12, No. of Rpts = 5, Premium $ = *380.56, DPMQ $ = 37.70, MRVSN $ = Hospira Pty Limited [HH]

- **heparin sodium 5000 international units/0.2 mL injection, 5 x 0.2 mL ampoules**
  - Code 1466E: Max Qty Packs = 1, No. of Rpts = 5, Premium $ = 19.44, DPMQ $ = 20.59, MRVSN $ = Hospira Pty Limited [HH]

- **heparin sodium 5000 international units/5 mL injection, 50 x 5 mL ampoules**
  - Code 1463B: Max Qty Packs = 1, No. of Rpts = 5, Premium $ = 71.86, DPMQ $ = 37.70, MRVSN $ = Pfizer Australia Pty Ltd [PF]

#### Platelet Aggregation Inhibitors excl. heparin

### Abciximab

- **Authority required (STREAMLINED)**
  - Code 4942: **Coronary artery disease**
  - **Treatment criteria:**
    - Patient must be undergoing percutaneous coronary balloon angioplasty.

---

Platelet aggregation inhibitors excl. heparin

ABCIXIMAB

Authority required (STREAMLINED)

4942

Coronary artery disease

Treatment criteria:

Patient must be undergoing percutaneous coronary balloon angioplasty.
**BLOOD AND BLOOD FORMING ORGANS**

**General**

**Authority required (STREAMLINED)**

4943

Coronary artery disease

**Treatment criteria:**

Patient must be undergoing percutaneous coronary atherectomy.

**Authority required (STREAMLINED)**

4915

Coronary artery disease

**Treatment criteria:**

Patient must be undergoing percutaneous coronary stent placement.

**abciximab 10 mg/5 mL injection, 1 x 5 mL vial**

<table>
<thead>
<tr>
<th>Code</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium</th>
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<tbody>
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<td>1453.45</td>
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**ASPIRIN**

**aspirin 100 mg tablet, 112**

<table>
<thead>
<tr>
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<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium</th>
<th>DPMQ</th>
<th>MRVSN</th>
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<tbody>
<tr>
<td>8202Q</td>
<td>1</td>
<td>1</td>
<td>8.21</td>
<td>9.36</td>
<td>* Mayne Pharma Aspirin [YT] * Spren 100 [QA]</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Astrix [YN]</td>
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**aspirin 300 mg tablet: effervescent, 96**

<table>
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<th>Code</th>
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<th>MRVSN</th>
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<tbody>
<tr>
<td>1010E</td>
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<td>8.51</td>
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<td>APO Clopidogrel [TX]</td>
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</tr>
<tr>
<td></td>
<td></td>
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<td></td>
<td></td>
<td>Clopidogrel AN [EA]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Iscover [AV]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Plavix [SW]</td>
</tr>
</tbody>
</table>

**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.

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.

**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.

**clopidogrel 75 mg tablet, 28**

<table>
<thead>
<tr>
<th>Code</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium</th>
<th>DPMQ</th>
<th>MRVSN</th>
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<td>* Clopidogrel-GA [GN] * Plidogrel [FM]</td>
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</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Clopidogrel AN [EA]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Clopidogrel Winthrop [WA]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Iscover [AV]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Plavix [SW]</td>
</tr>
</tbody>
</table>

**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 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

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.

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

<table>
<thead>
<tr>
<th>clopidogrel 75 mg tablet, 28</th>
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</thead>
<tbody>
<tr>
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<table>
<thead>
<tr>
<th>clopidogrel 75 mg tablet, 28</th>
</tr>
</thead>
<tbody>
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<td>Max Qty Packs</td>
</tr>
<tr>
<td>1</td>
</tr>
<tr>
<td>* Clopidogrel AN [EA]</td>
</tr>
<tr>
<td>* Clopidogrel Sandoz [SZ]</td>
</tr>
<tr>
<td>* Iscover [AV]</td>
</tr>
<tr>
<td>* Plavicor 75 [CR]</td>
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<tr>
<td>* Terry White Chemists Clopidogrel [TW]</td>
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<td>* Chem mart Clopidogrel [CH]</td>
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<tr>
<td>* Clopidogrel RBX [RA]</td>
</tr>
<tr>
<td>* Clopidogrel Winthrop [WA]</td>
</tr>
<tr>
<td>* Piax [AF]</td>
</tr>
<tr>
<td>* Plavix [SW]</td>
</tr>
</tbody>
</table>

**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.

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.

clopidogrel 75 mg tablet, 28

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clopidogrel Actavis [UA]</td>
</tr>
<tr>
<td>Clopidogrel GH [GQ]</td>
</tr>
<tr>
<td>Plidogrel [FM]</td>
</tr>
<tr>
<td>Clovid 75 [QA]</td>
</tr>
</tbody>
</table>

CLOPIDOGREL + ASPIRIN

- **Authority required (STREAMLINED)**
  - 3880
  - Treatment of acute coronary syndrome (myocardial infarction or unstable angina)

- **Authority required (STREAMLINED)**
  - 3219
  - Treatment following cardiac stent insertion

- **Authority required (STREAMLINED)**
  - 1722
  - Prevention of recurrence of myocardial infarction or unstable angina in patients with a history of symptomatic cardiac ischaemic events while on therapy with low-dose aspirin

**Note**

- Not for prophylaxis of DVT or peripheral arterial disease.

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.

clopidogrel 75 mg + aspirin 100 mg tablet, 30

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>APO-Clopidogrel/Aspirin 75/100 [TX]</td>
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<tr>
<td>Clopidogrel/Aspirin Actavis 75/100 [GN]</td>
</tr>
<tr>
<td>CoPlavix [SW]</td>
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<tr>
<td>DuoPlidogrel [GZ]</td>
</tr>
<tr>
<td>Terry White Chemists Clopidogrel/Aspirin 75/100 [TW]</td>
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<tr>
<td>Chem mart Clopidogrel/Aspirin 75/100 [CH]</td>
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<tr>
<td>Clopidogrel Winthrop plus aspirin [WA]</td>
</tr>
<tr>
<td>DuoCover [AV]</td>
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<tr>
<td>Piag Plus Aspirin [AF]</td>
</tr>
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</table>

DIPYRIDAMOLE

- **Restricted benefit**
  - Prevention of recurrence of ischaemic stroke or transient cerebral ischaemic events as adjunctive therapy with low-dose aspirin

- **Restricted benefit**
  - Prevention of recurrence of ischaemic stroke or transient cerebral ischaemic events where low-dose aspirin poses an unacceptable risk of gastrointestinal bleeding

- **Restricted benefit**
  - Prevention of recurrence of ischaemic stroke or transient cerebral ischaemic events where there is a history of anaphylaxis, urticaria or asthma within 4 hours of ingestion of aspirin, other salicylates, or NSAIDs

**Note**

Shared Care Model:

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

dipyridamole 200 mg capsule: modified release, 60 capsules

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>Persantin SR [BY]</td>
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</table>

DIPYRIDAMOLE + ASPIRIN

- **Restricted benefit**
  - Prevention of recurrence of ischaemic stroke or transient cerebral ischaemic events

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

dipyridamole 200 mg + aspirin 25 mg capsule: modified release, 60 capsules

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**EPTIFIBATIDE**

**Authority required (STREAMLINED)**

1884

Patients undergoing non-urgent percutaneous intervention with intracoronary stenting

eptifibatide 20 mg/10 mL injection, 1 x 10 mL vial

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eptifibatide 75 mg/100 mL injection, 1 x 100 mL vial

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**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.

prasugrel 10 mg tablet, 28

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prasugrel 5 mg tablet, 28

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**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.

TICAGRELOR Tablet 90 mg, 56

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**TIROFIBAN**

**Authority required (STREAMLINED)**

1729

Patients with high risk unstable angina who have new transient or persistent ST-T ischaemic changes and anginal pain lasting longer than 20 minutes

**Authority required (STREAMLINED)**

1730

Patients with high risk unstable angina who have new transient or persistent ST-T ischaemic changes and repetitive episodes of angina at rest or during minimal exercise in the previous 12 hours

**Authority required (STREAMLINED)**
**BLOOD AND BLOOD FORMING ORGANS**

1275

Patients with non-Q-wave myocardial infarction

**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.

tirofiban 12.5 mg/50 mL injection, 1 x 50 mL vial

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**Enzymes**

- **RETEPLASE**
  
  **Restricted benefit**
  
  Treatment of acute myocardial infarction within 6 hours of onset of attack
  
  **Note**
  
  Shared Care Model:
  
  For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

  reteplase 10 units (17.4 mg) injection [2 x 10 units vials] (&) inert substance diluent [2 x 10 mL syringes], 1 pack

<table>
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- **TENECTEPLASE**
  
  **Restricted benefit**
  
  Treatment of acute myocardial infarction within 12 hours of onset of attack
  
  **Note**
  
  Shared Care Model:
  
  For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

  tenecteplase 10 000 international units (50 mg) injection [1 x 50 mg vial] (&) inert substance diluent [1 x 10 mL syringe], 1 pack

<table>
<thead>
<tr>
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  tenecteplase 8000 international units (40 mg) injection [1 x 40 mg vial] (&) inert substance diluent [1 x 8 mL syringe], 1 pack

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  **Direct thrombin inhibitors**

- **BIVALIRUDIN**
  
  **Authority required (STREAMLINED)**
  
  4919
  
  Coronary artery disease
  
  **Treatment criteria:**
  
  Patient must be undergoing percutaneous coronary intervention.

  bivalirudin 250 mg injection, 1 x 250 mg vial

<table>
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<tr>
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</table>

- **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.
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.

dabigatran etexilate 110 mg capsule, 60
9321N  
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dabigatran etexilate 75 mg capsule, 60
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<td>121.01</td>
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</table>

**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.
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.

dabigatran etexilate 110 mg capsule, 10
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</table>

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

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

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<td>Pradaxa [BY]</td>
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</tbody>
</table>
- **DABIGATRAN**
  
  **Authority required (STREAMLINED)**
  
  **4269**
  Prevention of stroke or systemic embolism

  **Clinical criteria:**
  Patient must have non-valvular atrial fibrillation, **AND**
  Patient must have one or more risk factors for developing stroke or systemic embolism.

  Risk factors for developing stroke or systemic ischaemic embolism are:
  (i) Prior stroke (ischaemic or unknown type), transient ischaemic attack or non-central nervous system (CNS) systemic embolism;
  (ii) age 75 years or older;
  (iii) hypertension;
  (iv) diabetes mellitus;
  (v) heart failure and/or left ventricular ejection fraction 35% or less.

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

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

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

  Special Pricing Arrangements apply.

  **dabigatran etexilate 110 mg capsule, 60**
  
  2753X  
  Max.Qty Packs No. of Rpts Premium $  DPMQ $  MRVSN $  Brand Name and Manufacturer
  1  5 .. 96.25 37.70  Pradaxa [BY]

  **dabigatran etexilate 150 mg capsule, 60**
  
  2769R  
  Max.Qty Packs No. of Rpts Premium $  DPMQ $  MRVSN $  Brand Name and Manufacturer
  1  5 .. 96.25 37.70  Pradaxa [BY]

  **Direct factor Xa inhibitors**

- **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.

  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.

  **apixaban 2.5 mg tablet, 60**
  
  5061J  
  Max.Qty Packs No. of Rpts Premium $  DPMQ $  MRVSN $  Brand Name and Manufacturer
  1  .. .. 101.54 37.70  Eliquis [BQ]

- **APIXABAN**
  
  **Authority required (STREAMLINED)**
  
  **4269**
  Prevention of stroke or systemic embolism

  **Clinical criteria:**
  Patient must have non-valvular atrial fibrillation, **AND**
  Patient must have one or more risk factors for developing stroke or systemic embolism.

  Risk factors for developing stroke or systemic ischaemic embolism are:
  (i) Prior stroke (ischaemic or unknown type), transient ischaemic attack or non-central nervous system (CNS) systemic embolism;
  (ii) age 75 years or older;
  (iii) hypertension;
  (iv) diabetes mellitus;
(v) heart failure and/or left ventricular ejection fraction 35% or less.

Note

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

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

Special Pricing Arrangements apply.

apixaban 2.5 mg tablet, 60

<table>
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apixaban 5 mg tablet, 60

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**APIXABAN**

Authority required (STREAMLINED)

4382
Prevention of venous thromboembolism

Clinical criteria:
Patient must require up to 15 days of therapy.

Treatment criteria:
Patient must be undergoing total knee replacement.

Authority required (STREAMLINED)

4409
Prevention of venous thromboembolism

Clinical criteria:
Patient must require up to 15 days supply to complete a course of treatment.

Treatment criteria:
Patient must be undergoing total hip replacement.

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

apixaban 2.5 mg tablet, 30

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**APIXABAN**

Authority required (STREAMLINED)

4381
Prevention of venous thromboembolism

Clinical criteria:
Patient must require up to 10 days of therapy.

Treatment criteria:
Patient must be undergoing total knee replacement.

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.
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.

### Apixaban 2.5 mg tablet, 20

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<td>Eliquis [BO]</td>
</tr>
</tbody>
</table>

### Rivaroxaban

#### 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.
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.

#### Rivaroxaban 10 mg tablet, 10

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>9465E</td>
<td>1</td>
<td>39.65</td>
<td>37.70</td>
<td></td>
<td>Xarelto [BN]</td>
</tr>
</tbody>
</table>

### 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.
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.

#### Rivaroxaban Tablet 10 mg, 30

<table>
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<tr>
<td>9467G</td>
<td>1</td>
<td>101.14</td>
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#### Rivaroxaban 10 mg tablet, 15

<table>
<thead>
<tr>
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<tr>
<td>9466F</td>
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<td>54.16</td>
<td>37.70</td>
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<td>Xarelto [BN]</td>
</tr>
</tbody>
</table>
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 10 mg tablet, 10

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
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<th>DPMQ $</th>
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<tbody>
<tr>
<td>1</td>
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<td>..</td>
<td>39.65</td>
<td>37.70</td>
<td>Xarelto [BN]</td>
</tr>
</tbody>
</table>

- **RIVAROXABAN**
  - Authority required (STREAMLINED)
    - 4382
      - Prevention of venous thromboembolism
      - Clinical criteria: Patient must require up to 15 days of therapy.
      - Treatment criteria: Patient must be undergoing total knee replacement.
      - Note
        - No increase in the maximum quantity or number of units may be authorised.
        - 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.

rivaroxaban 10 mg tablet, 15

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
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<th>DPMQ $</th>
<th>MRVSN $</th>
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<tbody>
<tr>
<td>1</td>
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<td>..</td>
<td>54.16</td>
<td>37.70</td>
<td>Xarelto [BN]</td>
</tr>
</tbody>
</table>

- **RIVAROXABAN**
  - Authority required (STREAMLINED)
    - 4269
      - Prevention of stroke or systemic embolism
      - Clinical criteria: Patient must have non-valvular atrial fibrillation, **AND**
      - Patient must have one or more risk factors for developing stroke or systemic embolism.
      - Risk factors for developing stroke or systemic ischaemic embolism are:
        - (i) Prior stroke (ischaemic or unknown type), transient ischaemic attack or non-central nervous system (CNS) systemic embolism;
        - (ii) age 75 years or older;
        - (iii) hypertension;
        - (iv) diabetes mellitus;
        - (v) heart failure and/or left ventricular ejection fraction 35% or less.
      - Note
        - Shared Care Model:
          - For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.
          - No increase in the maximum quantity or number of units may be authorised.
          - No increase in the maximum number of repeats may be authorised.
          - Special Pricing Arrangements apply.

rivaroxaban 15 mg tablet, 28

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
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<th>Premium $</th>
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<tbody>
<tr>
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<td>..</td>
<td>94.85</td>
<td>37.70</td>
<td>Xarelto [BN]</td>
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</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.
      - Authority required (STREAMLINED)
        - 4260
Pulmonary embolism
Treatment Phase: Initial treatment
**Clinical criteria:**
Patient must have confirmed acute symptomatic pulmonary embolism.

**Note**
**Shared Care Model:**
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.
No increase in the maximum quantity or number of units may be authorised.
No increase in the maximum number of repeats may be authorised.
Special Pricing Arrangements apply.

**rivaroxaban 15 mg tablet, 42**

<table>
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<tr>
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<td>Xarelto [BN]</td>
</tr>
</tbody>
</table>

**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.

**Authority required (STREAMLINED)**

**4132**
Prevention of recurrent venous thromboembolism
Treatment Phase: Continuing treatment
**Clinical criteria:**
Patient must have a history of venous thromboembolism.

**Authority required (STREAMLINED)**

**4268**
Pulmonary embolism
Treatment Phase: Continuing treatment
**Clinical criteria:**
Patient must have confirmed acute symptomatic pulmonary embolism.

**Authority required (STREAMLINED)**

**4269**
Prevention of stroke or systemic embolism
**Clinical criteria:**
Patient must have non-valvular atrial fibrillation, **AND**
Patient must have one or more risk factors for developing stroke or systemic embolism.
Risk factors for developing stroke or systemic ischaemic embolism are:
(i) Prior stroke (ischaemic or unknown type), transient ischaemic attack or non-central nervous system (CNS) systemic embolism;
(ii) age 75 years or older;
(iii) hypertension;
(iv) diabetes mellitus;
(v) heart failure and/or left ventricular ejection fraction 35% or less.

**Note**
**Shared Care Model:**
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.
No increase in the maximum quantity or number of units may be authorised.
No increase in the maximum number of repeats may be authorised.
Special Pricing Arrangements apply.

**rivaroxaban 20 mg tablet, 28**

<table>
<thead>
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<th>No. of Rpts</th>
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<th>MRVSN $</th>
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<td>37.70</td>
<td>Xarelto [BN]</td>
</tr>
</tbody>
</table>

**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.

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.

| FONDAPARINUX SODIUM Injection 2.5 mg in 0.5 mL single dose pre-filled syringe, 2 |
|-----------------|-----------------|-----------------|-----------------|-----------------|
| Max.Qty Packs  | No. of Rpts  | Premium $ | DPMQ $ | MRVSN $ |
| 8775W          | 3.5           | ..         | *140.88 | 37.70  |

### 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.

| tranexamic acid 500 mg tablet, 100 |
|-----------------|-----------------|-----------------|-----------------|-----------------|
| Max.Qty Packs  | No. of Rpts  | Premium $ | DPMQ $ | MRVSN $ |
| 2180R          | 1              | 2            | 52.02  | 37.70  |

### ANTIANEMIC PREPARATIONS

#### IRON PREPARATIONS

**Iron bivalent, oral preparations**

### FERROUS FUMARATE

ferrous fumarate 200 mg (equivalent to 65.7 mg of elemental iron) tablet, 60

| ferrous fumarate 200 mg (equivalent to 65.7 mg of elemental iron) tablet, 60 |
|-----------------|-----------------|-----------------|-----------------|-----------------|
| Max.Qty Packs  | No. of Rpts  | Premium $ | DPMQ $ | MRVSN $ |
| 8985X          | 1              | 1            | 11.96  | 13.11  |

### FERROUS SULFATE

ferrous sulfate 30 mg/mL (equivalent to 6 mg/mL elemental iron) oral liquid, 250 mL

| ferrous sulfate 30 mg/mL (equivalent to 6 mg/mL elemental iron) oral liquid, 250 mL |
|-----------------|-----------------|-----------------|-----------------|-----------------|
| Max.Qty Packs  | No. of Rpts  | Premium $ | DPMQ $ | MRVSN $ |
| 8815Y          | †1             | 2            | 19.69  | 20.84  |

**Iron, parenteral preparations**

### IRON

iron (as ferric carboxymaltose) 500 mg/10 mL injection, 1 x 10 mL vial

| iron (as ferric carboxymaltose) 500 mg/10 mL injection, 1 x 10 mL vial |
|-----------------|-----------------|-----------------|-----------------|-----------------|
| Max.Qty Packs  | No. of Rpts  | Premium $ | DPMQ $ | MRVSN $ |
| 10104T         | 2              | 1            | *317.22 | 37.70  |

### IRON POLYMALTOSE

iron (as polymaltose) 100 mg/2 mL injection, 5 x 2 mL ampoules

| iron (as polymaltose) 100 mg/2 mL injection, 5 x 2 mL ampoules |
|-----------------|-----------------|-----------------|-----------------|-----------------|
| Max.Qty Packs  | No. of Rpts  | Premium $ | DPMQ $ | MRVSN $ |
| 2593L          | 1              | ..           | 31.88  | 33.03  | * Ferrosig [SI] |

**Authority required (STREAMLINED)**

### IRON POLYMALTOSE

| iron (as polymaltose) 100 mg/2 mL injection, 5 x 2 mL ampoules |
|-----------------|-----------------|-----------------|-----------------|-----------------|
| Max.Qty Packs  | No. of Rpts  | Premium $ | DPMQ $ | MRVSN $ |
| 2593L          | 1              | ..           | 31.88  | 33.03  | * Ferrum H [AS] |
BLOOD AND BLOOD FORMING ORGANS

Iron deficiency anaemia

Treatment criteria:
Patient must be undergoing chronic haemodialysis.

Iron (as polymaltose) 100 mg/2 mL injection, 5 x 2 mL ampoules

<table>
<thead>
<tr>
<th>Max.Qty</th>
<th>Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>5</td>
<td>..</td>
<td>31.88</td>
<td>33.03</td>
<td>* Ferrosig [SL] * Ferum H [AS]</td>
<td></td>
</tr>
</tbody>
</table>

Iron (as sucrose) 100 mg/5 mL injection, 5 x 5 mL ampoules

<table>
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<tr>
<th>Max.Qty</th>
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<th>No. of Rpts</th>
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<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tr>
<td>1</td>
<td>..</td>
<td>..</td>
<td>31.88</td>
<td>33.03</td>
<td>Venofer [AS]</td>
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</tr>
</tbody>
</table>

Iron in combination with folic acid

Ferro<f>us fumarate + Folic Acid

Ferrous fumarate 310 mg (equivalent to 100 mg elemental iron) + folic acid 350 microgram tablet, 60

<table>
<thead>
<tr>
<th>Max.Qty</th>
<th>Packs</th>
<th>No. of Rpts</th>
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<th>DPMQ $</th>
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</thead>
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<td>13.13</td>
<td>14.28</td>
<td>Ferro-f-tab [AE]</td>
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</tbody>
</table>

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.

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.

Hydroxocobalamin 1 mg/mL injection, 3 x 1 mL ampoules

<table>
<thead>
<tr>
<th>Max.Qty</th>
<th>Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>1</td>
<td></td>
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<td>11.67</td>
<td>12.82</td>
<td>* Vita-B12 [GH]</td>
<td></td>
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</tbody>
</table>

Hydroxocobalamin 1 mg/mL injection, 3 x 1 mL ampoules

<table>
<thead>
<tr>
<th>Max.Qty</th>
<th>Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>1</td>
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<td>..</td>
<td>11.67</td>
<td>12.82</td>
<td>* Hydrox-B12 [AS] * Neo-B12 [HH]</td>
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</table>

Folic acid and derivatives

Folic Acid

Folic acid 500 microgram tablet, 100

<table>
<thead>
<tr>
<th>Max.Qty</th>
<th>Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
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<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>2</td>
<td></td>
<td>..</td>
<td>*11.68</td>
<td>12.83</td>
<td>* Foitabs 500 [PP] * Megafol 0.5 [AF]</td>
<td></td>
</tr>
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</table>
### BLOOD AND BLOOD FORMING ORGANS

#### FOLIC ACID

**Note**

The 5 mg strength tablet should be used in malabsorption states only.

<table>
<thead>
<tr>
<th>folic acid 5 mg tablet, 100</th>
</tr>
</thead>
<tbody>
<tr>
<td>Max Qty Packs</td>
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<tr>
<td>1437P</td>
</tr>
</tbody>
</table>

#### BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS

### BLOOD AND RELATED PRODUCTS

**Blood substitutes and plasma protein fractions**

#### GELATIN-SUCCINYLATED

gelatin-succinylated 20 g/500 mL injection, 1 x 500 mL bag

<table>
<thead>
<tr>
<th>gelatin-succinylated 20 g/500 mL injection, 1 x 500 mL bag</th>
</tr>
</thead>
<tbody>
<tr>
<td>Max Qty Packs</td>
</tr>
<tr>
<td>8444K</td>
</tr>
</tbody>
</table>

#### PENTASTARCH + SODIUM CHLORIDE

**HYDROXYETHYL STARCH 130/0.4 I.V. infusion 30 g per 500 mL, 500 mL, 1**

<table>
<thead>
<tr>
<th>PENTASTARCH + SODIUM CHLORIDE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Max Qty Packs</td>
</tr>
<tr>
<td>9487H</td>
</tr>
</tbody>
</table>

### I.V. SOLUTIONS

**Solutions for parenteral nutrition**

#### GLUCOSE

**glucose 5% (50 g/1000 mL) injection, 1 x 1000 mL bag**

<table>
<thead>
<tr>
<th>glucose 5% (50 g/1000 mL) injection, 1 x 1000 mL bag</th>
</tr>
</thead>
<tbody>
<tr>
<td>Max Qty Packs</td>
</tr>
<tr>
<td>2245E</td>
</tr>
<tr>
<td>5106R</td>
</tr>
</tbody>
</table>

#### LACTATE + SODIUM CHLORIDE + POTASSIUM CHLORIDE + CALCIUM CHLORIDE DIHYDRATE

**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**

<table>
<thead>
<tr>
<th>LACTATE + SODIUM CHLORIDE + POTASSIUM CHLORIDE + CALCIUM CHLORIDE DIHYDRATE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Max Qty Packs</td>
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<tr>
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</table>

#### SODIUM CHLORIDE

**sodium chloride 0.9% (9 g/1000 mL) injection, 1 x 1000 mL bag**

<table>
<thead>
<tr>
<th>SODIUM CHLORIDE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Max Qty Packs</td>
</tr>
<tr>
<td>2264E</td>
</tr>
<tr>
<td>5212H</td>
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</tbody>
</table>

#### SODIUM CHLORIDE + GLUCOSE

**sodium chloride 0.18% (1.8 g/1000 mL) + glucose 4% (40 g/1000 mL) injection, 1 x 1000 mL bag**

<table>
<thead>
<tr>
<th>SODIUM CHLORIDE + GLUCOSE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Max Qty Packs</td>
</tr>
<tr>
<td>2281C</td>
</tr>
<tr>
<td>5214K</td>
</tr>
</tbody>
</table>
SODIUM GLUCONATE + SODIUM CHLORIDE + POTASSIUM CHLORIDE + MAGNESIUM CHLORIDE + SODIUM ACETATE TRIHYDRATE + GLUCOSE

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

<table>
<thead>
<tr>
<th>Max.Qty</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
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<td>*22.30</td>
<td>23.45</td>
<td>Plasma-Lyte 148 [BX]</td>
</tr>
</tbody>
</table>

ICATIBANT

Authority required
Anticipated emergency treatment of an acute attack of hereditary angioedema

Treatment Phase: Initial

Clinical criteria:
Patient must have confirmed diagnosis of C1-esterase inhibitor deficiency, AND
Patient must have been assessed to be at significant risk of an acute attack of hereditary angioedema, AND
The condition must be assessed by a clinical immunologist; OR
The condition must be assessed by a respiratory physician; OR
The condition must be assessed by a specialist allergist; OR
The condition must be assessed by a 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 date of the pathology report and name of the Approved Pathology Authority must be provided at the time of application.

Authority required
Anticipated emergency treatment of an acute attack of hereditary angioedema

Treatment Phase: Continuing

Clinical criteria:
Patient must have 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)

ICATIBANT Injection 30 mg (as acetate) in 3 mL single use pre-filled syringe, 1

<table>
<thead>
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<th>MRVSN $</th>
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<td>2571.70</td>
<td>37.70</td>
<td>Firazyr [ZI]</td>
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</tbody>
</table>

DIGOXIN

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

digoxin 250 microgram tablet, 100

<table>
<thead>
<tr>
<th>Max.Qty</th>
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<th>Premium $</th>
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<tr>
<td>1</td>
<td>1</td>
<td>11.05</td>
<td>12.20</td>
<td>*</td>
<td>*Sigmaxin [FM]</td>
</tr>
<tr>
<td></td>
<td></td>
<td>*2.94</td>
<td>13.99</td>
<td>12.20</td>
<td>*Lanoxin [QA]</td>
</tr>
</tbody>
</table>

digoxin 50 microgram/mL oral liquid, 60 mL

<table>
<thead>
<tr>
<th>Max.Qty</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>3</td>
<td>*41.46</td>
<td>37.70</td>
<td></td>
<td>Lanoxin [QA]</td>
</tr>
</tbody>
</table>
CARDIOVASCULAR SYSTEM

**ANTIARRHYTHMICS, CLASS I AND III**

### Antiarrhythmics, class la

**Disopyramide**

**Note**

Shared Care Model:

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

#### Disopyramide 100 mg capsule, 100

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>1</td>
<td>..</td>
<td>10.76</td>
<td>11.91</td>
<td>Sigmaxin-PG [FM]</td>
</tr>
<tr>
<td>2</td>
<td>2.95</td>
<td>13.71</td>
<td>11.91</td>
<td></td>
<td>Lanoxin-PG [QA]</td>
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</tbody>
</table>

#### Disopyramide 150 mg capsule, 100

<table>
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<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>5</td>
<td>..</td>
<td>29.47</td>
<td>30.62</td>
<td>Rythmodan [SW]</td>
</tr>
</tbody>
</table>

### Lignocaine

**Note**

Shared Care Model:

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

#### Lignocaine hydrochloride anhydrous 500 mg/5 mL injection, 10 x 5 mL ampoules

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
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<tbody>
<tr>
<td>1</td>
<td>..</td>
<td>..</td>
<td>29.93</td>
<td>31.08</td>
<td>Xylocard 500 [AP]</td>
</tr>
</tbody>
</table>

### Flecaïnide

**Caution**

Flecaïnide acetate should be avoided in patients with poor cardiac function.

**Restricted benefit**

Serious supraventricular cardiac arrhythmias

**Restricted benefit**

Serious ventricular cardiac arrhythmias where treatment is initiated in a hospital (in-patient or out-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.

#### Flecaïnide acetate 100 mg tablet, 60

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
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<th>MRVSN $</th>
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<tr>
<td>1</td>
<td>5</td>
<td>..</td>
<td>45.03</td>
<td>37.70</td>
<td>Flecatab [AF]</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Tambocor [IA]</td>
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</table>

#### Flecaïnide acetate 50 mg tablet, 60

<table>
<thead>
<tr>
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<tr>
<td>1</td>
<td>5</td>
<td>..</td>
<td>38.07</td>
<td>37.70</td>
<td>Tambocor [IA]</td>
</tr>
</tbody>
</table>

### Amiodarone

**Caution**

Amiodarone hydrochloride has been reported to cause frequent and potentially serious toxicity.

**Restricted benefit**

Severe cardiac arrhythmias
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.

amiodarone hydrochloride 100 mg tablet, 30

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
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<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>2344J</td>
<td>1 5</td>
<td>11.76</td>
<td>12.91</td>
<td></td>
<td>* Aratac 100 [AF]</td>
<td>* Cordarone X 100 [SW]</td>
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amiodarone hydrochloride 200 mg tablet, 30

<table>
<thead>
<tr>
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<th>Brand Name and Manufacturer</th>
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<tr>
<td>2343H</td>
<td>1 5</td>
<td>15.66</td>
<td>16.81</td>
<td></td>
<td>* Amiodarone Actavis [GN]</td>
<td>* Amiodarone Sandoz [SZ]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Aratac 200 [AF]</td>
<td>* Chem mart Amiodarone [CH]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Cordarone X 200 [SW]</td>
<td>* GenRx Amiodarone [GX]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Rithmik 200 [QA]</td>
<td>* Terry White Chemists</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Amiodarone [TW]</td>
</tr>
</tbody>
</table>

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.

sotalol hydrochloride 160 mg tablet, 60

<table>
<thead>
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<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>2043M</td>
<td>1 5</td>
<td>15.81</td>
<td>16.96</td>
<td></td>
<td>* APO-Sotalol [TX]</td>
<td>* Cardol [AF]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Chem mart Sotalol [CH]</td>
<td>* GenRx Sotalol [GX]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Solavert [QA]</td>
<td>* Sotalol Sandoz [SZ]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Terry White Chemists Sotalol</td>
<td>[TW]</td>
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</table>

sotalol hydrochloride 80 mg tablet, 60

<table>
<thead>
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<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>839BB</td>
<td>1 5</td>
<td>10.98</td>
<td>12.13</td>
<td></td>
<td>* APO-Sotalol [TX]</td>
<td>* Cardol [AF]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Solavert [QA]</td>
<td>* GenRx Sotalol [GX]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Sotalol Sandoz [SZ]</td>
<td></td>
</tr>
</tbody>
</table>

CARDIAC STIMULANTS EXCL. CARDIAC GLYCOSIDES

Adrenergic and dopaminergic agents

ADRENAline

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

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>1016L</td>
<td>1</td>
<td>20.68</td>
<td>21.83</td>
<td></td>
<td>Link Medical Products Pty Ltd</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>5004J</td>
<td>1</td>
<td>20.68</td>
<td>21.83</td>
<td></td>
<td>Link Medical Products Pty Ltd</td>
</tr>
</tbody>
</table>

Caution
EpiPen and Anapen products have different administration techniques and should not be prescribed to the same patient without training in their use.

Authority required
Acute allergic reaction with anaphylaxis
Treatment Phase: Initial sole PBS-subsidised supply for anticipated emergency treatment
Clinical criteria:
Patient must have been assessed to be at significant risk of anaphylaxis by, or in consultation with a clinical immunologist; OR
Patient must have been assessed to be at significant risk of anaphylaxis by, or in consultation with an allergist; OR
Patient must have been assessed to be at significant risk of anaphylaxis by, or in consultation with a paediatrician; OR Patient must have been assessed to be at significant risk of anaphylaxis by, or in consultation with a respiratory physician. The name of the specialist consulted must be provided at the time of application for initial supply.

**Authority required**

Acute allergic reaction with anaphylaxis

Treatment Phase: Initial sole PBS-subsidised supply for anticipated emergency treatment

**Clinical criteria:**

Patient must have been discharged from hospital or an emergency department after treatment with adrenaline for acute allergic reaction with anaphylaxis.

**Authority required**

Acute allergic reaction with anaphylaxis

Treatment Phase: Continuing sole PBS-subsidised supply for anticipated emergency treatment

**Clinical criteria:**

Patient must have previously been issued with an authority prescription for this drug.

**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.) Authority approvals will be limited to a maximum quantity of 2 auto-injectors (Anapen or EpiPen) at any one time. No applications for repeats will be authorised.

<table>
<thead>
<tr>
<th>Adrenaline 150 microgram/0.3 mL injection, 1 x 0.3 mL syringe</th>
</tr>
</thead>
<tbody>
<tr>
<td>340B</td>
</tr>
<tr>
<td>340B</td>
</tr>
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</table>

<table>
<thead>
<tr>
<th>Adrenaline 150 microgram/0.3 mL injection, 1 x 0.3 mL syringe</th>
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</thead>
<tbody>
<tr>
<td>8697R</td>
</tr>
<tr>
<td>8697R</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Adrenaline 300 microgram/0.3 mL injection, 1 x 0.3 mL syringe</th>
</tr>
</thead>
<tbody>
<tr>
<td>340K</td>
</tr>
<tr>
<td>340K</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Adrenaline 300 microgram/0.3 mL injection, 1 x 0.3 mL syringe</th>
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</thead>
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<tr>
<td>8698B</td>
</tr>
<tr>
<td>8698B</td>
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### VASODILATORS USED IN CARDIAC DISEASES

#### Organic nitrates

**GLYCERYL TRINITRATE**

<table>
<thead>
<tr>
<th>Glyceryl trinitrate 10 mg/24 hours patch, 30</th>
</tr>
</thead>
<tbody>
<tr>
<td>1516T</td>
</tr>
<tr>
<td>1516T</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Glyceryl trinitrate 10 mg/24 hours patch, 30</th>
</tr>
</thead>
<tbody>
<tr>
<td>8011P</td>
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<table>
<thead>
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</tr>
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<tbody>
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<tr>
<td>8028P</td>
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<table>
<thead>
<tr>
<th>Glyceryl trinitrate 15 mg/24 hours patch, 30</th>
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<td>8026K</td>
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</table>

<table>
<thead>
<tr>
<th>Glyceryl trinitrate 15 mg/24 hours patch, 30</th>
</tr>
</thead>
<tbody>
<tr>
<td>8119H</td>
</tr>
<tr>
<td>8119H</td>
</tr>
</tbody>
</table>
### GLYCERYL TRINITRATE

**Note**

The spray should not be inhaled.

#### GLYCERYL TRINITRATE

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
</tr>
</thead>
<tbody>
<tr>
<td>Transiderm-Nitro 25 [NV]</td>
<td>25.41</td>
<td>26.56</td>
<td></td>
</tr>
<tr>
<td>Nitro-Dur 5 [MK]</td>
<td>25.41</td>
<td>26.56</td>
<td></td>
</tr>
<tr>
<td>Minitran 5 [IA]</td>
<td>25.41</td>
<td>26.56</td>
<td></td>
</tr>
</tbody>
</table>

#### ISOSORBIDE DINITRATE

**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.

#### ISOSORBIDE MONONITRATE

**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.

#### NICORANDIL

**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.
nicorandil 20 mg tablet, 60

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
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<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>‡1</td>
<td>5</td>
<td>..</td>
<td>29.15</td>
<td>30.30</td>
<td>* Ikorel [SW]</td>
</tr>
</tbody>
</table>

**PERHEXILINE**

**Caution**
Regular monitoring of drug serum levels is recommended.

**Authority required (STREAMLINED)**

1023
Angina not responding to other 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.

perhexiline maleate 100 mg tablet, 100

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
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<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>1</td>
<td>5</td>
<td>..</td>
<td>62.96</td>
<td>37.70</td>
</tr>
</tbody>
</table>

**OTHER CARDIAC PREPARATIONS**

**Other cardiac preparations**

**IVABRADINE**

**Authority required**
Chronic heart failure

**Clinical criteria:**
Patient must be symptomatic with NYHA classes II or III, AND
Patient must be in sinus rhythm, AND
Patient must have a documented left ventricular ejection fraction (LVEF) of less than or equal to 35%, AND
Patient must have a resting heart rate at or above 77 bpm at the time ivabradine treatment is initiated, AND
Patient must receive concomitant optimal standard chronic heart failure treatment, which must include the maximum tolerated dose of a beta-blocker, unless contraindicated or not tolerated.

Resting heart rate should be measured by ECG after 5 minutes rest.
The ECG result must be documented in the patient’s medical records when treatment is initiated.

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

ivabradine 5 mg tablet, 56

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
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ivabradine 7.5 mg tablet, 56

<table>
<thead>
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**ANTIHYPERTENSIVES**

**ANTIADRENERGIC AGENTS, CENTRALLY ACTING**

**Methyldopa**

**METHYLDOPA**

metyldopa 250 mg tablet, 100

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
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<tr>
<td>1629R</td>
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<td>5</td>
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<td>16.88</td>
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# Cardiovacular System

## Clonidine

<table>
<thead>
<tr>
<th>Product Description</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clonidine hydrochloride 100 microgram tablet, 100</td>
<td>3145M</td>
<td>1</td>
<td>5</td>
<td>29.22</td>
<td>30.37</td>
<td>Catapres 100 [BY]</td>
</tr>
<tr>
<td>Clonidine hydrochloride 150 microgram tablet, 100</td>
<td>3141H</td>
<td>1</td>
<td>5</td>
<td>37.78</td>
<td>37.70</td>
<td>Catapres [BY]</td>
</tr>
</tbody>
</table>

## Moxonidine

**Restricted benefit**

**Hypertension**

**Clinical criteria:**
Patient must be receiving concurrent antihypertensive therapy.

### Moxonidine 200 microgram tablet, 30

<table>
<thead>
<tr>
<th>Product Description</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>Moxonidine 200 microgram tablet, 30</td>
<td>9019Q</td>
<td>1</td>
<td>5</td>
<td>19.87</td>
<td>21.02</td>
<td>Physiotens [GO]</td>
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### Moxonidine 400 microgram tablet, 30

<table>
<thead>
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<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Moxonidine 400 microgram tablet, 30</td>
<td>9020R</td>
<td>1</td>
<td>5</td>
<td>29.12</td>
<td>30.27</td>
<td>Physiotens [GO]</td>
</tr>
</tbody>
</table>

## Antidrenergic Agents, Peripherally Acting

### Alpha-adrenoceptor antagonists

## Prazosin

### Prazosin 1 mg tablet, 100

<table>
<thead>
<tr>
<th>Product Description</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prazosin 1 mg tablet, 100</td>
<td>1479W</td>
<td>1</td>
<td>5</td>
<td>11.00</td>
<td>12.15</td>
<td>APO-Prazosin [TX] Chem mart Prazosin [CH] Minipress [PF] Terry White Chemists Prazosin [TW]</td>
</tr>
</tbody>
</table>

### Prazosin 2 mg tablet, 100

<table>
<thead>
<tr>
<th>Product Description</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
</table>

### Prazosin 5 mg tablet, 100

<table>
<thead>
<tr>
<th>Product Description</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prazosin 5 mg tablet, 100</td>
<td>1478T</td>
<td>1</td>
<td>5</td>
<td>18.90</td>
<td>20.05</td>
<td>APO-Prazosin [TX] Chem mart Prazosin [CH] Minipress [PF] Terry White Chemists Prazosin [TW]</td>
</tr>
</tbody>
</table>

## Arteriolar Smooth Muscle, Agents Acting on

### Hydrazinophthalazine Derivatives

## Hydralazine

### Hydralazine hydrochloride 25 mg tablet, 100

<table>
<thead>
<tr>
<th>Product Description</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hydralazine hydrochloride 25 mg tablet, 100</td>
<td>1640H</td>
<td>2</td>
<td>2</td>
<td>17.64</td>
<td>18.79</td>
<td>Alphapress 25 [AF]</td>
</tr>
</tbody>
</table>

### Hydralazine hydrochloride 50 mg tablet, 100

<table>
<thead>
<tr>
<th>Product Description</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hydralazine hydrochloride 50 mg tablet, 100</td>
<td>1639G</td>
<td>2</td>
<td>2</td>
<td>19.36</td>
<td>20.51</td>
<td>Alphapress 50 [AF]</td>
</tr>
</tbody>
</table>

## Minoxidil

**Authority required (STREAMLINED)**

**4906**

**Severe refractory hypertension**

**Clinical criteria:**
The 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.

<table>
<thead>
<tr>
<th>minoxidil 10 mg tablet, 100</th>
</tr>
</thead>
<tbody>
<tr>
<td>2313R</td>
</tr>
<tr>
<td>Max Qty Packs: 1  No. of Rpts: 5  Premium $: 60.61  DPMQ $: 37.70  MRVSN $: 73.70  Brand Name and Manufacturer: Loniten [PF]</td>
</tr>
</tbody>
</table>

### DIURETICS

#### LOW-CEILING DIURETICS, THIAZIDES

**Thiazides, plain**

<table>
<thead>
<tr>
<th>hydrochlorothiazide 25 mg tablet, 100</th>
</tr>
</thead>
<tbody>
<tr>
<td>1484D</td>
</tr>
<tr>
<td>Max Qty Packs: 1  No. of Rpts: 1  Premium $: 21.58  DPMQ $: 22.73  Brand Name and Manufacturer: Dithiazide [PL]</td>
</tr>
</tbody>
</table>

#### LOW-CEILING DIURETICS, EXCL. THIAZIDES

**Sulfonamides, plain**

<table>
<thead>
<tr>
<th>chlorthalidone 25 mg tablet, 50</th>
</tr>
</thead>
<tbody>
<tr>
<td>1585K</td>
</tr>
<tr>
<td>Max Qty Packs: 1  No. of Rpts: 1  Premium $: 21.58  DPMQ $: 22.73  Brand Name and Manufacturer: Hygroton 25 [LM]</td>
</tr>
</tbody>
</table>

#### INDAPAMIDE

**indapamide hemihydrate 1.5 mg tablet: modified release, 90 tablets**

| 8532C                          |
| Max Qty Packs: 1  No. of Rpts: 1  Premium $: 19.64  DPMQ $: 20.79  Brand Name and Manufacturer: APO-Indapamide SR [TX] |

**indapamide hemihydrate 2.5 mg tablet, 90**

| 2436F                          |
| Max Qty Packs: 1  No. of Rpts: 1  Premium $: 15.59  DPMQ $: 16.74  Brand Name and Manufacturer: Chem mart Indapamide SR [CH] |

#### HIGH-CEILING DIURETICS

**Sulfonamides, plain**

<table>
<thead>
<tr>
<th>frusemide 10 mg/mL oral liquid, 30 mL</th>
</tr>
</thead>
<tbody>
<tr>
<td>2411X</td>
</tr>
<tr>
<td>Max Qty Packs: 1  No. of Rpts: 3  Premium $: 25.18  DPMQ $: 26.33  Brand Name and Manufacturer: Lasix [SW]</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>frusemide 20 mg/2 mL injection, 5 x 2 mL ampoules</th>
</tr>
</thead>
<tbody>
<tr>
<td>2413B</td>
</tr>
<tr>
<td>Max Qty Packs: 1  No. of Rpts: ..  Premium $: 8.63  DPMQ $: 9.78  Brand Name and Manufacturer: Frusemide-Claris [AE]</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>frusemide 40 mg tablet, 100</th>
</tr>
</thead>
<tbody>
<tr>
<td>2412Y</td>
</tr>
<tr>
<td>Max Qty Packs: 1  No. of Rpts: 1  Premium $: 8.15  DPMQ $: 9.30  Brand Name and Manufacturer: APO-Frusemide [TX]</td>
</tr>
</tbody>
</table>
### FRUSEMIDE

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>frusemide 20 mg tablet, 100</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>2414C</strong></td>
<td></td>
</tr>
<tr>
<td>Max Qty Packs</td>
<td>No. of Rpts</td>
</tr>
<tr>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### ETHACRYNIC ACID

**Restricted benefit**  
Patients hypersensitive to other oral diuretics

### POTASSIUM-SPARING AGENTS

**Aldosterone antagonists**

### EPLERENONE

**Caution**  
Serum electrolytes should be checked regularly

**Authority required (STREAMLINED)**

**4937**  
Heart failure with a left ventricular ejection fraction of 40% or less

**Clinical criteria:**  
The condition must occur within 3 to 14 days following an acute myocardial infarction, **AND**  
The treatment must be commenced within 14 days of an acute myocardial infarction.

The date of the acute myocardial infarction and the date of initiation of treatment with this drug must be documented in the patient's medical records when PBS-subsidised 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.

### SPIRONOLACTONE

**Caution**  
Serum electrolytes should be checked regularly.
Appropriate contraceptive measures should be taken by women of child-bearing age in whom spironolactone therapy has been initiated.

**spironolactone 100 mg tablet, 100**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>2340E</td>
<td>1</td>
<td>29.46</td>
<td>30.61</td>
<td>3.16</td>
<td>Spiractin 100 [AF]</td>
</tr>
<tr>
<td></td>
<td>5</td>
<td></td>
<td></td>
<td></td>
<td>Aldactone [PF]</td>
</tr>
</tbody>
</table>

**spironolactone 25 mg tablet, 100**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>2339D</td>
<td>1</td>
<td>12.53</td>
<td>13.68</td>
<td>2.59</td>
<td>Spiractin 25 [AF]</td>
</tr>
<tr>
<td></td>
<td>5</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.

**hydrochlorothiazide 50 mg + amiloride hydrochloride 5 mg tablet, 50**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1486F</td>
<td>2</td>
<td>13.84</td>
<td>14.99</td>
<td>*</td>
<td>Moduretic [AS]</td>
</tr>
</tbody>
</table>

### HYDROCHLOROTHIAZIDE + TRIAMTERENE

**Caution**
Serum electrolytes should be checked regularly.

**hydrochlorothiazide 25 mg + triamterene 50 mg tablet, 100**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1280J</td>
<td>1</td>
<td>13.23</td>
<td>14.38</td>
<td>*</td>
<td>Hydrene 25/50 [AF]</td>
</tr>
</tbody>
</table>

### PERIPHERAL VASODILATORS

**PERIPHERAL VASODILATORS**

*Other peripheral vasodilators*

### PHENOXYBENZAMINE

**Authority required**
Phaeochromocytoma

**Authority required**
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.

**phenoxybenzamine hydrochloride 10 mg capsule, 100**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1862B</td>
<td>1</td>
<td>1164.81</td>
<td>37.70</td>
<td>*</td>
<td>Dibenzyline [BZ]</td>
</tr>
<tr>
<td></td>
<td>5</td>
<td></td>
<td></td>
<td></td>
<td>Dibenzyline [GH]</td>
</tr>
</tbody>
</table>

**phenoxybenzamine hydrochloride 10 mg capsule, 100**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>9286R</td>
<td>1</td>
<td>6860.58</td>
<td>37.70</td>
<td>*</td>
<td>Dibenzyline [BZ]</td>
</tr>
</tbody>
</table>

**phenoxybenzamine hydrochloride 10 mg capsule, 30**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1166J</td>
<td>3</td>
<td>205.24</td>
<td>37.70</td>
<td>*</td>
<td>Dibenzyline [GH]</td>
</tr>
</tbody>
</table>

### BETA BLOCKING AGENTS

**BETA BLOCKING AGENTS**

*Beta blocking agents, non-selective*
### OXPRENOLOL

**oxprenolol hydrochloride 40 mg tablet, 100**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>2961W</td>
<td>1</td>
<td>5</td>
<td>48.58</td>
<td>37.70</td>
<td>Corbeton 40 [AF]</td>
</tr>
</tbody>
</table>

### PINDOLOL

**pindolol 15 mg tablet, 50**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>3065H</td>
<td>1</td>
<td>5</td>
<td>16.26</td>
<td>17.41</td>
<td>Visken 15 [NV]</td>
</tr>
</tbody>
</table>

**pindolol 5 mg tablet, 100**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>3062E</td>
<td>1</td>
<td>5</td>
<td>30.22</td>
<td>31.92</td>
<td>Barbloc 5 [AF]</td>
</tr>
</tbody>
</table>

### PROPRANOLOL

**propranolol hydrochloride 10 mg tablet, 100**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>2565B</td>
<td>1</td>
<td>5</td>
<td>3.75</td>
<td>14.28</td>
<td>Inderal [AP]</td>
</tr>
</tbody>
</table>

**propranolol hydrochloride 160 mg tablet, 50**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>2899N</td>
<td>1</td>
<td>5</td>
<td>12.05</td>
<td>13.95</td>
<td>Deralin 160 [AF]</td>
</tr>
</tbody>
</table>

**propranolol hydrochloride 40 mg tablet, 100**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>2566C</td>
<td>1</td>
<td>5</td>
<td>3.75</td>
<td>14.05</td>
<td>Inderal [AP]</td>
</tr>
</tbody>
</table>

### ATENOLOL

**atenolol 50 mg tablet, 30**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1081X</td>
<td>1</td>
<td>5</td>
<td>8.07</td>
<td>9.22</td>
<td>* APO-Atenolol [TX]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Atenolol AN [EA]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Atenolol-DG [GN]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Atenolol RBX [RA]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Atenolol Sandoz [SZ]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Atenolol GA [GN]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Atenolol Sandoz [SZ]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Tenolten 50 [DO]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Tensig [OA]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Terry White Chemists Atenol [TW]</td>
</tr>
</tbody>
</table>

### ATENOLOL

**atenolol 50 mg/10 mL oral liquid, 300 mL**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>2243C</td>
<td>1</td>
<td>5</td>
<td>27.78</td>
<td>28.93</td>
<td>Atenolol-AFT [AE]</td>
</tr>
</tbody>
</table>

### BISOPROLOL

**bisoprolol fumarate 10 mg tablet, 28**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>8606Y</td>
<td>1</td>
<td>5</td>
<td>33.83</td>
<td>34.98</td>
<td>* APO-Bisoprolol [TX]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Beprol 10 [DO]</td>
</tr>
</tbody>
</table>
CARDIOVASCULAR SYSTEM

**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

**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.

**METOPROLOL SUCCINATE Tablet 190 mg (controlled release), 30**

<table>
<thead>
<tr>
<th>Max.Pack</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>873R</td>
<td>1</td>
<td>10.23</td>
<td>NP</td>
<td>NP</td>
<td>Metatar [FM]</td>
</tr>
<tr>
<td>873N</td>
<td>1</td>
<td>9.04</td>
<td>20.22</td>
<td>NP</td>
<td>Metoprolor AN [EA]</td>
</tr>
<tr>
<td>873P</td>
<td>1</td>
<td>9.04</td>
<td>20.22</td>
<td>NP</td>
<td>Metoprolor Actavis [GN]</td>
</tr>
<tr>
<td>873Q</td>
<td>1</td>
<td>9.04</td>
<td>20.22</td>
<td>NP</td>
<td>Metoprolor RBX [RA]</td>
</tr>
<tr>
<td>1325R</td>
<td>1</td>
<td>9.04</td>
<td>20.22</td>
<td>NP</td>
<td>Mistrom [ER]</td>
</tr>
</tbody>
</table>

**METOPROLOL TARTRATE**

**METOPROLOL TARTRATE Tablet 100 mg, 60**

<table>
<thead>
<tr>
<th>Max.Pack</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
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<td>20.22</td>
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<td>Mistrom [ER]</td>
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</table>
### 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.

<table>
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<tr>
<th>Nebivolol 1.25 mg tablet, 28</th>
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<tbody>
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<td>Max Qty Packs</td>
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### CARVEDILOL

**Authority required (STREAMLINED)**

3234

Moderate to severe heart failure in a patient stabilised on conventional therapy which must include an ACE inhibitor or Angiotensin II antagonist, if tolerated

**Authority required (STREAMLINED)**

1735

Patients receiving this drug as a pharmaceutical benefit prior to 1 August 2002

**Note**

Continuing Therapy Only:
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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### CARDIOVASCULAR SYSTEM

**Cardiovascular System**

- Carvedilol generic [GQ]
- Chem mart Carvedilol 25 mg [CH]
- Dilatrend 25 [RO]
- Terry White Chemists Carvedilol 25 mg [TW]
- Voirop 25 [DO]
- Carvedilol Sandoz [SZ]
- Dicarz [AF]
- GN-Carvedilol [GN]
- Vediol 25 [QA]

**Carvedilol 3.125 mg tablet, 30**

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**Carvedilol 6.25 mg tablet, 60**

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<td>22.49</td>
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<td>Carvedilol Sandoz [SZ]</td>
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**Labetalol**

**Labetalol hydrochloride 100 mg tablet, 100**

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**Labetalol hydrochloride 200 mg tablet, 100**

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**Calcium Channel Blockers**

**Selective Calcium Channel Blockers with Mainly Vascular Effects**

- **Dihydropyridine derivatives**

**Amlodipine**

**Amlodipine 10 mg tablet, 30**

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<td>Pharmacor Amlodipine [CR]</td>
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<td>Amlo 10 [QA]</td>
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<td>Ozlodip [RA]</td>
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<td></td>
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<td>Amlodipine Sandoz [SZ]</td>
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**Amlodipine 5 mg tablet, 30**

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<td>Chem mart Amlodipine [CH]</td>
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<td>Norvapine [GN]</td>
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<td>Amlo-10 [RZ]</td>
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<td>Nordip [AF]</td>
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<td>Ozlodip [RA]</td>
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**Maximum Quantity Packs**

**No. of Rpts**

**Premium $**

**DPMQ $**

**MRVSN $**

**Brand Name and Manufacturer**

**Generic Name**

**Manufacturer**

**DPMQ $**

**MRVSN $**

**Brand Name and Manufacturer**

**Generic Name**

**Manufacturer**

**DPMQ $**

**MRVSN $**

**Brand Name and Manufacturer**

**Generic Name**

**Manufacturer**

**DPMQ $**

**MRVSN $**

**Brand Name and Manufacturer**

**Generic Name**

**Manufacturer**

**DPMQ $**

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**Generic Name**

**Manufacturer**

**DPMQ $**

**MRVSN $**

**Brand Name and Manufacturer**

**Generic Name**

**Manufacturer**

**DPMQ $**

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**DPMQ $**

**MRVSN $**

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**Generic Name**

**Manufacturer**

**DPMQ $**

**MRVSN $**

**Brand Name and Manufacturer**

**Generic Name**

**Manufacturer**

**DPMQ $**

**MRVSN $**

**Brand Name and Manufacturer**

**Generic Name**

**Manufacturer**

**DPMQ $**

**MRVSN $**

**Brand Name and Manufacturer**

**Generic Name**

**Manufacturer**
# Cardiopulmonary System

## Felodipine

<table>
<thead>
<tr>
<th>Felodipine 10 mg tablet: modified release, 30 tablets</th>
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<tbody>
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<td>Felodil XR 10 [QA]</td>
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## Lercanidipine

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<td>Ledip [RA]</td>
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<td>Lercan [QA]</td>
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<td>Ziroc [AF]</td>
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## Nifedipine

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### Phenylalkylamine derivatives

**VERAPAMIL**

**Caution**

The myocardial depressant effects of this drug and of beta-blocking drugs are additive.

**verapamil hydrochloride 160 mg capsule: modified release, 30 capsules**

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**verapamil hydrochloride 180 mg tablet: modified release, 30 tablets**

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**verapamil hydrochloride 240 mg capsule: modified release, 30 capsules**

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**verapamil hydrochloride 240 mg tablet: modified release, 30 tablets**

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**verapamil hydrochloride 40 mg tablet, 100**

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<th>MRVSN $</th>
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<tr>
<td>1248Q</td>
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<td>12.36</td>
<td>13.51</td>
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<td>Anpec 40 [AF]</td>
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**verapamil hydrochloride 80 mg tablet, 100**

<table>
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<tbody>
<tr>
<td>1250T</td>
<td>1</td>
<td>15.35</td>
<td>16.50</td>
<td></td>
<td>* Anpec 80 [AF]</td>
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</tbody>
</table>

**Benzothiazepine derivatives**

**DILTIAZEM**

**Caution**

The myocardial depressant effects of this drug and of beta-blocking drugs are additive.

**diltiazem hydrochloride 180 mg capsule: modified release, 30 capsules**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
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<tr>
<td>1312C</td>
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<td>15.41</td>
<td>16.56</td>
<td></td>
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**diltiazem hydrochloride 240 mg capsule: modified release, 30 capsules**

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<tr>
<td>1313D</td>
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<td>18.44</td>
<td>19.59</td>
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</table>

**diltiazem hydrochloride 360 mg capsule: modified release, 30 capsules**

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<td>23.23</td>
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**diltiazem hydrochloride 60 mg tablet, 90**

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<tr>
<td>1335G</td>
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<td>14.56</td>
<td>15.71</td>
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<td>* Cardizem [SW]</td>
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### AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM

#### ACE INHIBITORS, PLAIN

**ACE inhibitors, plain**
CARDIOVASCULAR SYSTEM

- **CAPTOPRIL**

  **Caution**
  Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

  **captopril 12.5 mg tablet, 90**
  1147J Max Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer Brand Name and Manufacturer
  1 5 .. 12.07 13.22 * Captopril Sandoz [SZ] * GenRx Captopril [GX]
  * Zedace [AF]

  **captopril 25 mg tablet, 90**
  1148K Max Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer Brand Name and Manufacturer
  1 5 .. 14.45 15.60 * Captopril Sandoz [SZ] * GenRx Captopril [GX]
  * Zedace [AF]

  **captopril 50 mg tablet, 90**
  1149L Max Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer Brand Name and Manufacturer
  1 5 .. 21.93 23.08 * Captopril Sandoz [SZ] * GenRx Captopril [GX]
  * Zedace [AF]

  **captopril 5 mg/mL oral liquid, 95 mL**
  8760C Max Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer Brand Name and Manufacturer
  1 5 .. 112.16 37.70 Capoten [QA]

- **CAPTOPRIL**

  **Restricted benefit**
  Patients unable to take a solid dose form of an ACE inhibitor.

  **Population criteria:**
  Patient must not be pregnant. Use of ACE inhibitors is contraindicated during pregnancy since these drugs have been associated with foetal death in utero.

  **captopril 5 mg/mL oral liquid, 95 mL**
  8760C Max Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer Brand Name and Manufacturer
  ‡1 5 .. 112.16 37.70 Capoten [QA]

- **ENALAPRIL**

  **Caution**
  Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

  **enalapril maleate 10 mg tablet, 30**
  1368B Max Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer Brand Name and Manufacturer
  1 5 .. 11.38 12.53 * Acetec [AL] * APO-Enalapril [TX]
  * Auspril [OA] * Chem mart Enalapril [CH]
  * Enalapril Actavis [UA] * Enalapril AN [EA]
  * Enalapril-GA [GN] * GenRx Enalapril [GX]
  * Enalapril Sandoz [SZ] * Terry White Chemists Enalapril
  * Malean [FM] [TW]

  **enalapril maleate 20 mg tablet, 30**
  1369C Max Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer Brand Name and Manufacturer
  1 5 .. 12.65 13.80 * Acetec [AL] * APO-Enalapril [TX]
  * Auspril [OA] * Chem mart Enalapril [CH]
  * Enalapril Actavis [UA] * Enalapril AN [EA]
  * Enalapril-GA [GN] * GenRx Enalapril [GX]
  * Enalapril Sandoz [SZ] * Terry White Chemists Enalapril
  * Malean [FM] [TW]

  **enalapril maleate 5 mg tablet, 30**
  1370D Max Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer Brand Name and Manufacturer
  1 5 .. 9.57 10.72 * Acetec [AL] * APO-Enalapril [TX]
  * Auspril [OA] * Chem mart Enalapril [CH]
  * Enalapril Actavis [UA] * Enalapril AN [EA]
  * Enalapril-GA [GN] * GenRx Enalapril [GX]
  * Enalapril Sandoz [SZ] * Terry White Chemists Enalapril
  * Malean [FM] [TW]
CARDIOVASCULAR SYSTEM

- FOSINOPRIL
  
  **Caution**
  Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

  **fosinopril sodium 10 mg tablet, 30**
  
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<tr>
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<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
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<th>Brand Name and Manufacturer</th>
<th>Brand Name and Manufacturer</th>
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<tr>
<td>1182F</td>
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<td>5</td>
<td>12.88</td>
<td>14.03</td>
<td>* Fosinopril [TX]</td>
<td>* Fosipril 10 [QA]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* GenRx Fosinopril [GX]</td>
<td>* Monopril [BQ]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Monopril [BQ]</td>
<td></td>
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</tbody>
</table>

- LISISNORPRIL
  
  **Caution**
  Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

  **lisinopril 10 mg tablet, 30**
  
<table>
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<tr>
<th>Max.Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
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<th>Brand Name and Manufacturer</th>
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<td>2457H</td>
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<td>11.60</td>
<td>12.75</td>
<td>* APO-Lisinopril [TX]</td>
<td>* Auro-Lisinopril 10 [DO]</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Chem mart Lisinopril [CH]</td>
<td>* Fibsol 10 [QA]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Lisinopril AN [EA]</td>
<td>* Lisinopril-DRLA [RZ]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Lisinopril-GA [GN]</td>
<td>* Lisinopril generichealth [GQ]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Lisinopril Sandoz [SZ]</td>
<td>* Terry White Chemists</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Zinopril 10 [AL]</td>
<td>* Lisinopril TW</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2.82</td>
<td>14.42</td>
<td>12.75</td>
<td>* Zestril [AP]</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>3.21</td>
<td>14.81</td>
<td>12.75</td>
<td>* Prinivil 10 [MK]</td>
<td></td>
</tr>
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</table>

  **lisinopril 20 mg tablet, 30**
  
<table>
<thead>
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<th>Brand Name and Manufacturer</th>
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<tr>
<td>2458J</td>
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<td>12.87</td>
<td>14.02</td>
<td>* APO-Lisinopril [TX]</td>
<td>* Auro-Lisinopril 20 [DO]</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Chem mart Lisinopril [CH]</td>
<td>* Fibsol 20 [QA]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Lisinopril AN [EA]</td>
<td>* Lisinopril-DRLA [RZ]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Lisinopril-GA [GN]</td>
<td>* Lisinopril generichealth [GQ]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Lisinopril Sandoz [SZ]</td>
<td>* Terry White Chemists</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2.81</td>
<td>15.68</td>
<td>14.02</td>
<td>* Zestril [AP]</td>
<td>* Lisinopril TW</td>
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<tr>
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<td></td>
<td>3.21</td>
<td>16.08</td>
<td>14.02</td>
<td>* Prinivil 20 [MK]</td>
<td></td>
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  **lisinopril 5 mg tablet, 30**
  
<table>
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<tr>
<td>2456G</td>
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<td>* Auro-Lisinopril 5 [DO]</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Chem mart Lisinopril [CH]</td>
<td>* Fibsol 5 [QA]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Lisinopril AN [EA]</td>
<td>* Lisinopril-DRLA [RZ]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Lisinopril-GA [GN]</td>
<td>* Lisinopril generichealth [GQ]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Lisinopril Sandoz [SZ]</td>
<td>* Terry White Chemists</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2.82</td>
<td>12.82</td>
<td>11.15</td>
<td>* Zestril [AP]</td>
<td>* Lisinopril TW</td>
</tr>
</tbody>
</table>

- PERINDOPRIL
  
  **Caution**
  Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

  **Note**
  Pharmaceutical benefits that have the form perindopril erbumine tablet 2 mg and pharmaceutical benefits that have the form perindopril arginine tablet 2.5 mg are equivalent for the purposes of substitution.

  **perindopril arginine 2.5 mg tablet, 30**
  
<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
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<th>Brand Name and Manufacturer</th>
<th>Brand Name and Manufacturer</th>
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<tr>
<td>9006B</td>
<td>1</td>
<td>5</td>
<td>11.30</td>
<td>10.80</td>
<td>* Coversyl 2.5mg [SE]</td>
<td>* PREXUM 2.5 [RX]</td>
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</tbody>
</table>
### 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 5 mg are equivalent for the purposes of substitution.

### QUINAPRIL

**Caution**
Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.
### CARDIOVASCULAR SYSTEM

#### quinapril 5 mg tablet, 30%

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium</th>
<th>DPMQ</th>
<th>MRVSN</th>
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<tbody>
<tr>
<td>1</td>
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<td>10.36</td>
<td>11.51</td>
<td>* Quinapril [AS]</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Quinapril generichealth [GQ]</td>
</tr>
</tbody>
</table>

#### ramipril 2.5 mg tablet [7 tablets] (&) ramipril 5 mg tablet [21 tablets] (&) ramipril 10 mg capsule [10 capsules], 1 pack

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium</th>
<th>DPMQ</th>
<th>MRVSN</th>
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<tbody>
<tr>
<td>1</td>
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<td>12.15</td>
<td>13.30</td>
<td>Ttritace Titration Pack [SW]</td>
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</tbody>
</table>

#### ramipril 10 mg capsule, 30%

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium</th>
<th>DPMQ</th>
<th>MRVSN</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>1</td>
<td>5</td>
<td>.</td>
<td>12.56</td>
<td>13.71</td>
<td>* APO-Ramipril [TX]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* GenRx Ramipril [GX]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Prilace 10 [QA]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Ramipril CH [EA]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Ramipril generichealth [GQ]</td>
</tr>
<tr>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>* Ramipril Winthrop [WA]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Tritace 10 mg [SW]</td>
</tr>
<tr>
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<td></td>
<td></td>
<td></td>
<td>* Vascalace Caps 10 [DO]</td>
</tr>
</tbody>
</table>

#### ramipril 10 mg tablet, 30%

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium</th>
<th>DPMQ</th>
<th>MRVSN</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>1</td>
<td>5</td>
<td>.</td>
<td>12.56</td>
<td>13.71</td>
<td>* APO-Ramipril [TX]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Ramipril AN [EA]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Ramipril Sandoz [SZ]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Terry White Chemists Ramipril[TW]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Tritace [SW]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Vascalace Caps 10 [DO]</td>
</tr>
</tbody>
</table>

#### ramipril 1.25 mg capsule, 30%

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium</th>
<th>DPMQ</th>
<th>MRVSN</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>1</td>
<td>5</td>
<td>.</td>
<td>8.55</td>
<td>9.70</td>
<td>* APO-Ramipril [TX]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Ramipril GA [GN]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Tryzan Caps 1.25 [AF]</td>
</tr>
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</table>

#### ramipril 1.25 mg tablet, 30%

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium</th>
<th>DPMQ</th>
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<tbody>
<tr>
<td>1</td>
<td>5</td>
<td>.</td>
<td>8.55</td>
<td>9.70</td>
<td>* APO-Ramipril [TX]</td>
</tr>
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<td></td>
<td></td>
<td></td>
<td>* Ramipril AN [EA]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Ramipril Sandoz [SZ]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Terry White Chemists Ramipril[TW]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Tritace [SW]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Vascalace 1.25 [DO]</td>
</tr>
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</table>

**General**

**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.
**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.

---

**ramipril 2.5 mg capsule, 30**

<table>
<thead>
<tr>
<th>Max Qty</th>
<th>Packs</th>
<th>No. of Rpts</th>
<th>Premium</th>
<th>DPMQ</th>
<th>MRVSN</th>
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</thead>
<tbody>
<tr>
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<td></td>
<td>5</td>
<td>9.38</td>
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* APO-Ramipril [TX]
* Ramipril-GA [GN]
* Ramipril generichealth [GQ]
* Terry White Chemists Ramipril [TW]
* Vascalace Caps 2.5 [DO]

---

**ramipril 2.5 mg tablet, 30**

<table>
<thead>
<tr>
<th>Max Qty</th>
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<th>No. of Rpts</th>
<th>Premium</th>
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<th>MRVSN</th>
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<tbody>
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<td>10.53</td>
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* APO-Ramipril [TX]
* Prilace 2.5 [QA]
* Ramipril AN [EA]
* Ramipril Sandoz [SZ]
* Terry White Chemists Ramipril [TW]
* Tryzan Caps 2.5 [AF]
* Vascalace 2.5 [DO]

---

**ramipril 5 mg capsule, 30**

<table>
<thead>
<tr>
<th>Max Qty</th>
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<th>MRVSN</th>
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* APO-Ramipril [TX]
* Pharmacaor Ramipril 5 [CR]
* Ramipril generichealth [GQ]
* Tryzan Caps 5 [AF]
* Vascalace Caps 5 [DO]

---

**ramipril 5 mg tablet, 30**

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<tr>
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<td>11.20</td>
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* APO-Ramipril [TX]
* Prilace 5 [QA]
* Ramipril AN [EA]
* Ramipril Sandoz [SZ]
* Terry White Chemists Ramipril [TW]
* Tryzan Tabs 5 [AF]
* Vascalace 5 [DO]

---

**TRANODOLAPRIL**

**Caution**

Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

---

**trandolapril 1 mg capsule, 28**

<table>
<thead>
<tr>
<th>Max Qty</th>
<th>Packs</th>
<th>No. of Rpts</th>
<th>Premium</th>
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* APO-Trandolapril [TX]
* Tranalpha [AF]
* Dolapril 1 [QA]
* Trandolapril-DP [GN]

---

**trandolapril 2 mg capsule, 28**

<table>
<thead>
<tr>
<th>Max Qty</th>
<th>Packs</th>
<th>No. of Rpts</th>
<th>Premium</th>
<th>DPMQ</th>
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* APO-Trandolapril [TX]
* Tranalpha [AF]
* Dolapril 2 [QA]
* Trandolapril-DP [GN]
### ACE INHIBITORS, COMBINATIONS

#### ACE inhibitors and diuretics

- **ENALAPRIL + HYDROCHLOROTHIAZIDE**
  
  **Caution**
  
  Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

  **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.

- **ENALAPRIL + HYDROCHLOROTHIAZIDE**
  
  **Caution**
  
  Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

  **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.

- **FOSINOPRIL + HYDROCHLOROTHIAZIDE**
  
  **Caution**
  
  Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

  **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.

- **PERINDOPRIL + INADPAMIDE**
  
  **Caution**
  
  Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

  **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-like diuretic.

Note
Pharmaceutical benefits that have the form perindopril with indapamide hemihydrate tablet (containing 4 mg perindopril erbumine-1.25 mg indapamide hemihydrate) and pharmaceutical benefits that have the form perindopril with indapamide hemihydrate tablet (containing 5 mg perindopril arginine-1.25 mg indapamide hemihydrate) are equivalent for the purposes of substitution.

<table>
<thead>
<tr>
<th>Schedule of Pharmaceutical Benefits</th>
<th>117</th>
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</thead>
</table>

perindopril arginine 5 mg + indapamide hemihydrate 1.25 mg tablet, 30

<table>
<thead>
<tr>
<th></th>
<th>Max Qty</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>2845R</td>
<td>1</td>
<td>5</td>
<td>..</td>
<td>19.80</td>
<td>20.95</td>
<td>* Coversyl Plus 5mg/1.25mg [SE]</td>
<td>* Prexum Combi 5/1.25 [RX]</td>
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</table>

perindopril erbumine 4 mg + indapamide hemihydrate 1.25 mg tablet, 30

<table>
<thead>
<tr>
<th></th>
<th>Max Qty</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>8449Q</td>
<td>1</td>
<td>5</td>
<td>..</td>
<td>19.80</td>
<td>20.95</td>
<td>* Chem mart Perindopril/Indapamide 4/1.25 [CH]</td>
<td>* GenRx Perindopril/Indapamide 4/1.25 [GX]</td>
</tr>
<tr>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Idaprex Combi 4/1.25 [SZ]</td>
<td>* Indosyl Combi 4/1.25 [QA]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Perindo Combi 4/1.25 [AF]</td>
<td>* Perindopril and Indapamide CH 4/1.25 [EA]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Perindopril Combi Actavis 4/1.25 [GN]</td>
<td>* Perindopril/Indapamide GH 4/1.25 [GQ]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Terry White Chemists Perindopril/Indapamide 4/1.25 [TW]</td>
<td></td>
</tr>
</tbody>
</table>

**QUINAPRIL + HYDROCHLOROTHIAZIDE**

**Caution**
Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

**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.

<table>
<thead>
<tr>
<th>quinapril 10 mg + hydrochlorothiazide 12.5 mg tablet, 30</th>
</tr>
</thead>
<tbody>
<tr>
<td>8588C Max Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $</td>
</tr>
<tr>
<td>1 5 .. 14.13 15.28</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>quinapril 20 mg + hydrochlorothiazide 12.5 mg tablet, 30</th>
</tr>
</thead>
<tbody>
<tr>
<td>8590D Max Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $</td>
</tr>
<tr>
<td>1 5 .. 15.34 16.49</td>
</tr>
</tbody>
</table>

**ACE inhibitors and calcium channel blockers**

**LERCANIDIPINE + ENALAPRIL**

**Caution**
Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

**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.

<table>
<thead>
<tr>
<th>lercanidipine hydrochloride 10 mg + enalapril maleate 10 mg tablet, 28</th>
</tr>
</thead>
<tbody>
<tr>
<td>9144G Max Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $</td>
</tr>
<tr>
<td>1 5 .. 14.13 15.28</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>lercanidipine hydrochloride 10 mg + enalapril maleate 20 mg tablet, 28</th>
</tr>
</thead>
<tbody>
<tr>
<td>9145H Max Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $</td>
</tr>
<tr>
<td>1 5 .. 15.30 16.45</td>
</tr>
</tbody>
</table>

**PERINDOPRIL + AMLODIPINE**

**Caution**
Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

**Restricted benefit**
Hypertension

**Clinical criteria:**
The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
The condition must be inadequately controlled with an ACE inhibitor; **OR**
The condition must be inadequately controlled with a dihydropyridine calcium channel blocker.

**Restricted benefit**

**Stable coronary heart disease**

**Clinical criteria:**
The treatment must not be for the initiation of therapy for coronary heart disease, **AND**
The condition must be stabilised by treatment with perindopril and amlodipine at the same doses.

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>perindopril arginine 10 mg + amlodipine 10 mg tablet, 30</strong></td>
</tr>
<tr>
<td><strong>perindopril arginine 10 mg + amlodipine 5 mg tablet, 30</strong></td>
</tr>
<tr>
<td><strong>perindopril arginine 5 mg + amlodipine 10 mg tablet, 30</strong></td>
</tr>
<tr>
<td><strong>perindopril arginine 5 mg + amlodipine 5 mg tablet, 30</strong></td>
</tr>
</tbody>
</table>

**RAMIPRIL + FELODIPINE**

**Caution**
Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

**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.

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>ramipril 2.5 mg + felodipine 2.5 mg tablet: modified release, 30 tablets</strong></td>
</tr>
<tr>
<td><strong>ramipril 5 mg + felodipine 5 mg tablet: modified release, 30 tablets</strong></td>
</tr>
</tbody>
</table>

**TRANDOLAPRIL + VERAPAMIL**

**Caution**
Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

**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.

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>trandolapril 2 mg + verapamil hydrochloride 180 mg tablet: modified release, 28 tablets</strong></td>
</tr>
<tr>
<td><strong>trandolapril 4 mg + verapamil hydrochloride 240 mg tablet: modified release, 28 tablets</strong></td>
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</tbody>
</table>

**ANGIOTENSIN II ANTAGONISTS, PLAIN**

**Angiotensin II antagonists, plain**
### Candesartan

**Candesartan cilexetil 16 mg tablet, 30**

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
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<th>Premium $</th>
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<tbody>
<tr>
<td>1</td>
<td>5</td>
<td>..</td>
<td>18.97</td>
<td>20.12</td>
<td>* Adesan [AF]</td>
<td>* APO-Candesartan [TX]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Auro-Candesartan 16 [DO]</td>
<td>* Candesartan AN [EA]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Candesartan Aspen 16 [QA]</td>
<td>* Candesartan-GA [GN]</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Candesartan GH [GG]</td>
<td>* Candesartan RBX [RA]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Candesartan Sandoz [SZ]</td>
<td>* Chem mart Candesartan [CH]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Pharmacor Candesartan 16</td>
<td>* Terry White Chemists</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>[CR]</td>
<td>Candesartan [TW]</td>
</tr>
<tr>
<td></td>
<td></td>
<td>11.59</td>
<td>20.56</td>
<td>20.12</td>
<td>* Atacand [AP]</td>
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**Candesartan cilexetil 32 mg tablet, 30**

<table>
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<tr>
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<th>MRVSN $</th>
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<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>1</td>
<td>5</td>
<td>..</td>
<td>21.53</td>
<td>22.68</td>
<td>* Adesan [AF]</td>
<td>* APO-Candesartan [TX]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Auro-Candesartan 32 [DO]</td>
<td>* Candesartan AN [EA]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Candesartan Aspen 32 [QA]</td>
<td>* Candesartan-GA [GN]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Candesartan GH [GG]</td>
<td>* Candesartan RBX [RA]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Candesartan Sandoz [SZ]</td>
<td>* Chem mart Candesartan [CH]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Pharmacor Candesartan 32</td>
<td>* Terry White Chemists</td>
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<td></td>
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<td>11.57</td>
<td>23.10</td>
<td>22.68</td>
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<td>Candesartan [TW]</td>
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**Candesartan cilexetil 4 mg tablet, 30**

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<th>MRVSN $</th>
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<th>Brand Name and Manufacturer</th>
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<td>8.13</td>
<td>9.28</td>
<td>* Adesan [AF]</td>
<td>* APO-Candesartan [TX]</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>* Auro-Candesartan 4 [DO]</td>
<td>* Candesartan AN [EA]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Candesartan Aspen 4 [QA]</td>
<td>* Candesartan-GA [GN]</td>
</tr>
<tr>
<td></td>
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<td></td>
<td></td>
<td></td>
<td>* Candesartan GH [GG]</td>
<td>* Candesartan RBX [RA]</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Candesartan Sandoz [SZ]</td>
<td>* Chem mart Candesartan [CH]</td>
</tr>
<tr>
<td></td>
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<td></td>
<td></td>
<td></td>
<td>* Pharmacor Candesartan 4</td>
<td>* Terry White Chemists</td>
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**Candesartan cilexetil 8 mg tablet, 30**

<table>
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<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>1</td>
<td>5</td>
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<td>10.84</td>
<td>11.99</td>
<td>* Adesan [AF]</td>
<td>* APO-Candesartan [TX]</td>
</tr>
<tr>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>* Auro-Candesartan 8 [DO]</td>
<td>* Candesartan AN [EA]</td>
</tr>
<tr>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>* Candesartan Aspen 8 [QA]</td>
<td>* Candesartan-GA [GN]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Candesartan GH [GG]</td>
<td>* Candesartan RBX [RA]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Candesartan Sandoz [SZ]</td>
<td>* Chem mart Candesartan [CH]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Pharmacor Candesartan 8</td>
<td>* Terry White Chemists</td>
</tr>
</tbody>
</table>

### Eprosartan

**Eprosartan 400 mg tablet, 28**

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>2</td>
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<td>3.50</td>
<td>24.48</td>
<td>22.13</td>
<td>Teveten [GO]</td>
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</tbody>
</table>

**Eprosartan 600 mg tablet, 28**

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>5</td>
<td>3.50</td>
<td>28.07</td>
<td>25.72</td>
<td>Teveten [GO]</td>
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### Eprosartan

**Authority required**

- Adverse effects occurring with all of the base-priced drugs

**Authority required**

- Drug interactions occurring with all of the base-priced drugs

**Authority required**

- Drug interactions expected to occur with all of the base-priced drugs

**Authority required**

- Transfer to a base-priced drug would cause patient confusion resulting in problems with compliance

**Eprosartan 400 mg tablet, 28**

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### CARDIOVASCULAR SYSTEM

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**IRBESARTAN**  
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**LOSARTAN**  
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**OLMESARTAN MEDOXOMIL**  
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**OLMESARTAN MEDOXOMIL**  
Authority required  
Adverse effects occurring with all of the base-priced drugs  
Authority required  
Drug interactions occurring with all of the base-priced drugs  
Authority required
Drug interactions expected to occur with all of the base-priced drugs

**Authority required**

Transfer to a base-priced drug would cause patient confusion resulting in problems with compliance

### olmesartan medoxomil 20 mg tablet, 30

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### olmesartan medoxomil 40 mg tablet, 30

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### TELMISARTAN

telmisartan 40 mg tablet, 28

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### telmisartan 80 mg tablet, 28

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### VALSARTAN

valsartan 160 mg tablet, 28

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valsartan 40 mg tablet, 28

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valsartan 80 mg tablet, 28

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### VALSARTAN

**Note**

No applications for increased maximum quantities and/or repeats will be authorised for the 320 mg tablet.

valsartan 320 mg tablet, 28

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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.

#### candesartan cilexetil 16 mg + hydrochlorothiazide 12.5 mg tablet, 30

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##### 2.00 24.84 23.99  A: Atacand Plus 16/12.5 [AP]

#### candesartan cilexetil 32 mg + hydrochlorothiazide 12.5 mg tablet, 30

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##### 2.02 27.90 27.03  A: Atacand Plus 32/12.5 [AP]

#### candesartan cilexetil 32 mg + hydrochlorothiazide 25 mg tablet, 30

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##### 2.00 29.33 28.48  A: Atacand Plus 32/25 [AP]

### EPROSARTAN + HYDROCHLOROTHIAZIDE

#### Restricted benefit

Hypertension

### Clinical criteria:
The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
The condition must be inadequately controlled with an angiotensin II antagonist; **OR**
The condition must be inadequately controlled with a thiazide diuretic.

#### eprosartan 600 mg + hydrochlorothiazide 12.5 mg tablet, 28

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<th>No. of Rpts</th>
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### IRBESARTAN + HYDROCHLOROTHIAZIDE

#### Restricted benefit

Hypertension
**Clinical criteria:**
The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
The condition must be inadequately controlled with an angiotensin II antagonist; **OR**
The condition must be inadequately controlled with a thiazide diuretic.

### irbesartan 150 mg + hydrochlorothiazide 12.5 mg tablet, 30

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### irbesartan 300 mg + hydrochlorothiazide 12.5 mg tablet, 30

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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.

### olmesartan medoxomil 20 mg + hydrochlorothiazide 12.5 mg tablet, 30

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### olmesartan medoxomil 40 mg + hydrochlorothiazide 12.5 mg tablet, 30

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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.

#### telmisartan 40 mg + hydrochlorothiazide 12.5 mg tablet, 28

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#### telmisartan 80 mg + hydrochlorothiazide 12.5 mg tablet, 28

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#### telmisartan 80 mg + hydrochlorothiazide 25 mg tablet, 28

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### 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.

#### valsartan 160 mg + hydrochlorothiazide 12.5 mg tablet, 28

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#### valsartan 160 mg + hydrochlorothiazide 25 mg tablet, 28

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</table>
### VALSARTAN + HYDROCHLOROTHIAZIDE

**Restricted benefit**

**Hypertension**

**Clinical criteria:**
- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with an angiotensin II antagonist; **OR**
- The condition must be inadequately controlled with a thiazide diuretic.

**Note**
- No applications for increased maximum quantities and/or repeats will be authorised for the tablets containing 320 mg valsartan.

#### valsartan 80 mg + hydrochlorothiazide 12.5 mg tablet, 28

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#### valsartan 320 mg + hydrochlorothiazide 12.5 mg tablet, 28

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<td>* Co-Diovan 320/12.5 [NV]</td>
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#### valsartan 320 mg + hydrochlorothiazide 25 mg tablet, 28

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<td>* Co-Diovan 320/25 [NV]</td>
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### 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.

#### amlodipine 10 mg + valsartan 160 mg tablet, 28

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#### amlodipine 5 mg + valsartan 160 mg tablet, 28

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#### amlodipine 5 mg + valsartan 320 mg tablet, 28

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### OLMESARTAN MEDOXOMIL + AMLODIPINE

**Restricted benefit**

**Hypertension**

**Clinical criteria:**
- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with an angiotensin II antagonist; **OR**
- The condition must be inadequately controlled with a dihydropyridine calcium channel blocker.
### General

<table>
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<tr>
<th>Olmesartan Medoxomil 20 mg + Amlodipine 5 mg Tablet, 30</th>
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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.

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### Angiotensin II Antagonists, Other Combinations

#### Amlodipine + Valsartan + Hydrochlorothiazide

#### Restricted Benefit

*Hypertension*

**Clinical criteria:**

- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with concomitant treatment with two of the following: an angiotensin II antagonist, a dihydropyridine calcium channel blocker or a thiazide diuretic.

<table>
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OLMESARTAN + AMLODIPINE + HYDROCHLOROTHIAZIDE

Restricted benefit

Hypertension

Clinical criteria:
The treatment must not be for the initiation of anti-hypertensive therapy, AND
The condition must be inadequately controlled with concomitant treatment with two of the following: an angiotensin II antagonist, a dihydropyridine calcium channel blocker or a thiazide diuretic.

olmesartan medoxomil 20 mg + amlodipine 5 mg + hydrochlorothiazide 12.5 mg tablet, 30

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olmesartan medoxomil 40 mg + amlodipine 10 mg + hydrochlorothiazide 12.5 mg tablet, 30

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olmesartan medoxomil 40 mg + amlodipine 10 mg + hydrochlorothiazide 25 mg tablet, 30

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olmesartan medoxomil 40 mg + amlodipine 5 mg + hydrochlorothiazide 12.5 mg tablet, 30

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olmesartan medoxomil 40 mg + amlodipine 5 mg + hydrochlorothiazide 25 mg tablet, 30

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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

atorvastatin 10 mg tablet, 30

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<th>Max Qty</th>
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atorvastatin 20 mg tablet, 30

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atorvastatin 40 mg tablet, 30

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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.

atorvastatin 80 mg tablet, 30

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atorvastatin 10 mg tablet, 30

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atorvastatin 20 mg tablet, 30

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<th>MRVSN $</th>
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atorvastatin 40 mg tablet, 30

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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.

<table>
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<th>Fluvastatin 20 mg capsule, 28</th>
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<th>Fluvastatin 80 mg tablet: modified release, 28 tablets</th>
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### FLUVASTATIN

**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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### PRAVASTATIN

**Restricted benefit**

For use in patients that meet the criteria set out in the General Statement for Lipid-Lowering Drugs.

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**Note**

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

<table>
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<tr>
<th>Pravastatin sodium 10 mg tablet, 30</th>
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**Note**

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

#### Pravastatin Sodium

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**PRAVASTATIN**

**Restricted benefit**

For use in patients who meet the criteria set out in the General Statement for Lipid-Lowering Drugs, and who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.

**Note**

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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

#### ROSUVASTATIN

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#### ROSUVASTATIN

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**Clinical criteria:**
The treatment must not be prescribed for hypercholesterolaemia if the patient has heterozygous familial hypercholesterolaemia.
### 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.

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

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

**General**

- **rosuvastatin 40 mg tablet, 30**
  - **Max Qty Packs**: 3405F
  - **No. of Rpts**: 11
  - **Premium $**: 46.43
  - **DPMQ $**: 37.70
  - **MRVSN $**: 34.05
  - **Brand Name and Manufacturer**: Blooms the Chemist Rosuvastatin [IB]
  - **Brand Name and Manufacturer**: Chem mart Rosuvastatin [CH]
  - **Brand Name and Manufacturer**: Crouva 40 [ZP]
  - **Brand Name and Manufacturer**: Rosuvastatin Actavis 40 [GN]
  - **Brand Name and Manufacturer**: Rosuvastatin RBX [RA]

- **rosuvastatin 5 mg tablet, 30**
  - **Max Qty Packs**: 3402C
  - **No. of Rpts**: 11
  - **Premium $**: 20.32
  - **DPMQ $**: 17.87
  - **MRVSN $**: 16.37
  - **Brand Name and Manufacturer**: Blooms the Chemist Rosuvastatin [IB]
  - **Brand Name and Manufacturer**: Chem mart Rosuvastatin [CH]
  - **Brand Name and Manufacturer**: Crouva 5 [ZP]
  - **Brand Name and Manufacturer**: Rosuvastatin Actavis 5 [GN]
  - **Brand Name and Manufacturer**: Rosuvastatin RBX [RA]

### SIMVASTATIN

**Restricted benefit**

- **simvastatin 10 mg tablet, 30**
  - **Max Qty Packs**: 2011W
  - **No. of Rpts**: 5
  - **Premium $**: 8.95
  - **DPMQ $**: 10.10
  - **MRVSN $**: 12.28
  - **Brand Name and Manufacturer**: Lipex 10 [FR]
  - **Brand Name and Manufacturer**: Zocor [MK]

- **simvastatin 20 mg tablet, 30**
  - **Max Qty Packs**: 2012X
  - **No. of Rpts**: 5
  - **Premium $**: 9.92
  - **DPMQ $**: 11.07
  - **MRVSN $**: 12.28
  - **Brand Name and Manufacturer**: Lipex 20 [FR]
  - **Brand Name and Manufacturer**: Zocor [MK]

- **simvastatin 40 mg tablet, 30**
  - **Max Qty Packs**: 8173E
  - **No. of Rpts**: 5
  - **Premium $**: 11.31
  - **DPMQ $**: 12.46
  - **MRVSN $**: 14.64
  - **Brand Name and Manufacturer**: Lipex 40 [FR]
  - **Brand Name and Manufacturer**: Zocor [MK]
### SIMVASTATIN

#### Restricted benefit

For use in patients who meet the criteria set out in the General Statement for Lipid-Lowering Drugs, and who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements

#### Note

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

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### simvastatin 5 mg tablet, 30

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### simvastatin 80 mg tablet, 30

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### simvastatin 10 mg tablet, 30

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### simvastatin 40 mg tablet, 30

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### simvastatin 5 mg tablet, 30

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### 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.

| fenofibrate 145 mg tablet, 30
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| fenofibrate 48 mg tablet, 60
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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.

| gemfibrozil 600 mg tablet, 60
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General

- **GEMFIBROZIL**
  
  **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 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.

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

  **gemfibrozil 600 mg tablet, 60**

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<td>* GenRx Gemfibrozil [GX]</td>
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<td>* Lipigem [AF]</td>
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  **Bile acid sequestrants**

- **CHOLESTYRAMINE**
  
  **cholestyramine 4 g oral liquid: powder for, 50 x 4.7 g sachets**

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- **CHOLESTYRAMINE**
  
  **cholestyramine 4 g oral liquid: powder for, 50 x 4.7 g sachets**

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<td>37.70</td>
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- **COLESTIPOL HYDROCHLORIDE**
  
  **colestipol hydrochloride 5 g granules, 120 x 5 g sachets**

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- **COLESTIPOL HYDROCHLORIDE**
  
  **colestipol hydrochloride 5 g granules, 120 x 5 g sachets**

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- **Other lipid modifying agents**

- **EZETIMIBE**
  
  **Authority required (STREAMLINED)**

  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
CARDIOVASCULAR SYSTEM

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 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)

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 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 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)**

3731

Patients eligible for PBS-subsidised lipid-lowering medication (according to the criteria set out in the General Statement for Lipid-Lowering Drugs) where treatment with an HMG CoA reductase inhibitor (statin) is contraindicated

**Authority required (STREAMLINED)**

3730

Patients eligible for PBS-subsidised lipid-lowering medication (according to the criteria set out in the General Statement for Lipid-Lowering Drugs) where treatment with an HMG CoA reductase inhibitor (statin) must be discontinued or reduced because the patient developed a clinically important product-related adverse event during treatment with a statin. A clinically important product-related adverse event is defined as follows:

(i) Severe myalgia (muscle symptoms without creatine kinase elevation) which is proven to be temporally associated with statin treatment; or

(ii) Myositis (clinically important creatine kinase elevation, with or without muscle symptoms) demonstrated by results twice the upper limit of normal on a single reading or a rising pattern on consecutive measurements and which is unexplained by other causes; or

(iii) Unexplained, persistent elevations of serum transaminases (greater than 3 times the upper limit of normal) during treatment with a statin

**Authority required (STREAMLINED)**

1991

Homozygous sitosterolaemia

**Authority required (STREAMLINED)**

2438

Patients with homozygous familial hypercholesterolaemia who are eligible for PBS-subsidised lipid-lowering medication (according to the criteria set out in the General Statement for Lipid-Lowering Drugs), in combination with an HMG CoA reductase inhibitor (statin)

**Note**

Continuing Therapy Only:

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

HMG CoA reductase inhibitors in combination with other lipid modifying agents

- ATORVASTATIN (&) EZETIMIBE

**Authority required (STREAMLINED)**

### 4068

**Hypercholesterolaemia**

**Clinical criteria:**

The treatment must be in conjunction with dietary therapy and exercise, AND

Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), AND

Patient must have coronary heart disease.

Inadequate control with a statin is defined as follows:

1. where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

2. where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

### 4085

**Hypercholesterolaemia**

**Clinical criteria:**

The treatment must be in conjunction with dietary therapy and exercise, AND

Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), AND

Patient must have diabetes mellitus.

Inadequate control with a statin is defined as follows:

1. where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

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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

2. where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.
Inadequate control with a statin is defined as follows:

Patient must have hypertension.

The treatment must be in conjunction with dietary therapy and exercise, AND

Patient must have heterozygous familial hypercholesterolaemia.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

Authority required (STREAMLINED)

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)

Hypercholesterolaemia

Clinical criteria:
The treatment must be in conjunction with dietary therapy and exercise, AND

Patient must have a family history of coronary heart disease.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

Authority required (STREAMLINED)

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)**

**4087 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.

<table>
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**Authority required (STREAMLINED)**

**4085 Hypercholesterolaemia**

**Clinical criteria:**

The treatment must be in conjunction with dietary therapy and exercise, AND

Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), AND

Patient must have diabetes mellitus. |
| Inadequate control with a statin is defined as follows: |
| (1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or |
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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

2. where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

4069

**Hypercholesterolaemia**

**Clinical criteria:**

The treatment must be in conjunction with dietary therapy and exercise, **AND**

Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**

Patient must have heterozygous familial hypercholesterolaemia.

Inadequate control with a statin is defined as follows:

1. where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

2. where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**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 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.
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.
EZETIMIBE + SIMVASTATIN

**Authority required (STREAMLINED)**

**4065**

**Hypercholesterolaemia**

**Clinical criteria:**
The treatment must be in conjunction with dietary therapy and exercise, AND Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), AND Patient must have coronary heart disease.

Inadequate control with a statin is defined as follows:

1. where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient’s medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

2. where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient’s medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

**4085**

**Hypercholesterolaemia**

**Clinical criteria:**
The treatment must be in conjunction with dietary therapy and exercise, AND Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), AND Patient must have diabetes mellitus.

Inadequate control with a statin is defined as follows:

1. where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient’s medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

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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

2. where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient’s medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

**4069**

**Hypercholesterolaemia**
Clinical criteria: The treatment must be in conjunction with dietary therapy and exercise, **AND** Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND** Patient must have heterozygous familial hypercholesterolaemia.

Inadequate control with a statin is defined as follows:

1. where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e., a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient’s medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

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**Authority required (STREAMLINED)**

4096 Hypercholesterolaemia

Clinical criteria: The treatment must be in conjunction with dietary therapy and exercise, **AND** Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND** Patient must have symptomatic cerebrovascular disease.

Inadequate control with a statin is defined as follows:

1. where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e., a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient’s medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

2. where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e., a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient’s medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

4120 Hypercholesterolaemia

Clinical criteria: The treatment must be in conjunction with dietary therapy and exercise, **AND** Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND** Patient must have a family history of coronary heart disease.

Inadequate control with a statin is defined as follows:

1. where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e., a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient’s medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

2. where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e., a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient’s medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

4121 Hypercholesterolaemia

Clinical criteria: The treatment must be in conjunction with dietary therapy and exercise, **AND** Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND** Patient must have hypertension.

Inadequate control with a statin is defined as follows:

1. where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e., a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be
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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)**

**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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**EZETIMIBE + SIMVASTATIN**

**Authority required (STREAMLINED)**

**4068**
Hypercholesterolaemia

**Clinical criteria:**
The treatment must be in conjunction with dietary therapy and exercise, **AND**
Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
Patient must have coronary heart disease.

Inadequate control with a statin is defined as follows:
(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or
(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

**4085**
Hypercholesterolaemia

**Clinical criteria:**
The treatment must be in conjunction with dietary therapy and exercise, **AND**
Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
Patient must have diabetes mellitus.

Inadequate control with a statin is defined as follows:
(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or
(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be...
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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

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/L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient’s medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

**4069**

Hypercholesterolaemia

**Clinical criteria:**

The treatment must be in conjunction with dietary therapy and exercise, AND

Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), AND

Patient must have heterozygous familial hypercholesterolaemia.

Inadequate control with a statin is defined as follows:

1. where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient’s medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

2. where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol/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/L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient’s medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

**4120**

Hypercholesterolaemia

**Clinical criteria:**

The treatment must be in conjunction with dietary therapy and exercise, AND

Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), AND

Patient must have a family history of coronary heart disease.
Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

4121

**Hypercholesterolaemia**

**Clinical criteria:**
The treatment must be in conjunction with dietary therapy and exercise, **AND**
Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
Patient must have hypertension.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

4097

**Hypercholesterolaemia**

**Clinical criteria:**
Patient must have homozygous familial hypercholesterolaemia, **AND**
Patient must be eligible for PBS-subsidised lipid-lowering medication (according to the criteria set out in the General Statement for Lipid-Lowering Drugs).

**Authority required (STREAMLINED)**

4147

**Hypercholesterolaemia**

**Clinical criteria:**
Patient must be eligible for PBS-subsidised lipid-lowering medication (according to the criteria set out in the General Statement for Lipid-Lowering Drugs), **AND**
Patient must have developed a clinically important product-related adverse event during treatment with an HMG CoA reductase inhibitor (statin) necessitating a reduction in the statin dose.

A clinically important product-related adverse event is defined as follows:

(i) Severe myalgia (muscle symptoms without creatine kinase elevation) which is proven to be temporally associated with statin treatment; or

(ii) Myositis (clinically important creatine kinase elevation, with or without muscle symptoms) demonstrated by results twice the upper limit of normal on a single reading or a rising pattern on consecutive measurements and which is unexplained by other causes; or

(iii) Unexplained, persistent elevations of serum transaminases (greater than 3 times the upper limit of normal) during treatment with a statin.

**Note**

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

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**ezetimibe 10 mg + simvastatin 10 mg tablet, 30**

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**ROSUVASTATIN (&) EZETIMIBE**

**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 coronary heart disease.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

**4085**

**Hypercholesterolaemia**

**Clinical criteria:**

The treatment must be in conjunction with dietary therapy and exercise, AND Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), AND Patient must have diabetes mellitus.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

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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

(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)**

**4089**

**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
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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-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or
(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

Authority required (STREAMLINED)

4121 Hypercholesterolaemia

Clinical criteria:
The treatment must be in conjunction with dietary therapy and exercise, AND
Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), AND
Patient must have hypertension.

Inadequate control with a statin is defined as follows:
(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be
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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 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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### ROSUVASTATIN (&) EZETIMIBE

**Authority required (STREAMLINED)**

4068
Hypercholesterolaemia
Clinical criteria: 
The treatment must be in conjunction with dietary therapy and exercise, AND Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), AND Patient must have coronary heart disease.

Inadequate control with a statin is defined as follows: 
(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient’s medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or (2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient’s medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

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| Rosuvastatin 10 mg tablet [30] (&) ezetimibe 10 mg tablet [30], 1 pack |
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| Max Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
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| Rosuvastatin 20 mg tablet [30] (&) ezetimibe 10 mg tablet [30], 1 pack |
|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
| Max Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
| 10201X | 1 | 5 | .. | 81.48 | 37.70 | Rosuzet Composite Pack [MK] |

| Rosuvastatin 40 mg tablet [30] (&) ezetimibe 10 mg tablet [30 tablets], 1 pack |
|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
| Max Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
| 10207F | 1 | 5 | .. | 85.86 | 37.70 | Rosuzet Composite Pack [MK] |
(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

**4086**

**Hypercholesterolaemia**

**Clinical criteria:**
The treatment must be in conjunction with dietary therapy and exercise, AND
Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), AND
Patient must have peripheral vascular disease.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

**4069**

**Hypercholesterolaemia**

**Clinical criteria:**
The treatment must be in conjunction with dietary therapy and exercise, AND
Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), AND
Patient must have heterozygous familial hypercholesterolaemia.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

**4096**

**Hypercholesterolaemia**

**Clinical criteria:**
The treatment must be in conjunction with dietary therapy and exercise, AND
Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), AND
Patient must have symptomatic cerebrovascular disease.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

**4120**

**Hypercholesterolaemia**

**Clinical criteria:**
The treatment must be in conjunction with dietary therapy and exercise, **AND**
Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
Patient must have a family history of coronary heart disease.

Inadequate control with a statin is defined as follows:

1. where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or
2. where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

**Authority required (STREAMLINED)**

### 4121

**Hypercholesterolaemia**

**Clinical criteria:**
The treatment must be in conjunction with dietary therapy and exercise, **AND**
Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
Patient must have hypertension.

Inadequate control with a statin is defined as follows:

1. where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; 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:

1. Severe myalgia (muscle symptoms without creatine kinase elevation) which is proven to be temporally associated with statin treatment; or
2. 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
3. Unexplained, persistent elevations of serum transaminases (greater than 3 times the upper limit of normal) during treatment with a statin.

**Note**

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

- **AMLODIPINE + ATORVASTATIN**

  **Restricted benefit**
  For use in patients who have hypertension and/or angina and who meet the criteria set out in the General Statement for Lipid-Lowering Drugs, and who are currently receiving treatment with a dihydropyridine calcium channel blocker

  **Restricted benefit**
  For use in patients who have hypertension and/or angina and who meet the criteria set out in the General Statement for Lipid-Lowering Drugs, and whose blood pressure and/or angina is inadequately controlled with other classes of antihypertensive and/or anti-anginal agent, and in whom adjunctive therapy with a dihydropyridine calcium channel blocker would be appropriate

  **Restricted benefit**
  For use in patients who have hypertension and/or angina and who meet the criteria set out in the General Statement for Lipid-Lowering Drugs, and who are intolerant of the side effects of other classes of antihypertensive and/or anti-anginal agent, and in whom replacement therapy with a dihydropyridine calcium channel blocker would be appropriate

### amiodipine 10 mg + atorvastatin 10 mg tablet, 30

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<thead>
<tr>
<th>9053L</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
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<td>* Cadatin 10/10 [FZ]</td>
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<td></td>
<td>* Caduet 10/10 [PF]</td>
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### amiodipine 10 mg + atorvastatin 20 mg tablet, 30

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<td>* Cadatin 10/20 [FZ]</td>
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<td>* Caduet 10/20 [PF]</td>
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<td></td>
<td>* Terry White Chemists Amlodipine/Atorvastatin 10/20 [TW]</td>
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<td>* Cadatin 10/40 [FZ]</td>
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<td>* Caduet 10/80 [PF]</td>
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### amiodipine 5 mg + atorvastatin 10 mg tablet, 30

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<td>* Blooms the Chemist Amlodipine/Atorvastatin 5/10 [IB]</td>
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</table>
### DERMATOLOGICALS

### ANTIFUNGALS FOR DERMATOLOGICAL USE

#### ANTIFUNGALS FOR TOPICAL USE

#### Antibiotics

**NYSTATIN**

*Authority required (STREAMLINED) 2354*

Treatment of a fungal or a yeast infection in an Aboriginal or a Torres Strait Islander person

nystatin 100 000 international units/g cream, 15 g

<table>
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<th>1698J</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
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<th>DPMQ $</th>
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<td>*</td>
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<td>18.90</td>
<td>20.05</td>
<td>Mycostatin [FM]</td>
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*Imidazole and triazole derivatives*

**KETOCONAZOLE**

*Authority required (STREAMLINED) 2354*

Treatment of a fungal or a yeast infection in an Aboriginal or a Torres Strait Islander person

ketoconazole 1% (10 mg/g) shampoo, 100 mL

<table>
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<th>9025B</th>
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<th>No. of Rpts</th>
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<td>‡1</td>
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<td>17.94</td>
<td>19.09</td>
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<td>Nizoral 1% [JT]</td>
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**DERMATOLOGICALS**

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<th>Schedule of Pharmaceutical Benefits</th>
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<tr>
<td><strong>General</strong></td>
</tr>
<tr>
<td><strong>ketoconazole 2% (20 mg/g) cream, 30 g</strong></td>
</tr>
<tr>
<td>9024Y</td>
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<tr>
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</tr>
</tbody>
</table>

| **ketoconazole 2% (20 mg/g) shampoo, 60 mL** |
| 1574W                              | Max Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer  |
|                                     | 1             | 1           | 18.65     | 19.80   |          | Nizoral 2% [JT]              |

**MICONAZOLE**

**Authority required (STREAMLINED)**

**2354**
Treatment of a fungal or a yeast infection in an Aboriginal or a Torres Strait Islander person

<table>
<thead>
<tr>
<th>miconazole 2% solution, 30 mL</th>
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<table>
<thead>
<tr>
<th>miconazole nitrate 2% (20 mg/g) cream, 30 g</th>
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<tbody>
<tr>
<td>9027D</td>
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</table>

<table>
<thead>
<tr>
<th>miconazole nitrate 2% (20 mg/g) cream, 70 g</th>
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<table>
<thead>
<tr>
<th>miconazole nitrate 2% (20 mg/g) powder: dusting, 30 g</th>
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<tbody>
<tr>
<td>9029F</td>
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**Other antifungals for topical use**

**TERBINAFINE**

**Authority required (STREAMLINED)**

**2354**
Treatment of a fungal or a yeast infection in an Aboriginal or a Torres Strait Islander person

<table>
<thead>
<tr>
<th>terbinafine hydrochloride 1% cream, 15 g</th>
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</tbody>
</table>

**ANTIFUNGALS FOR SYSTEMIC USE**

**Antifungals for systemic use**

**GRISEOFULVIN**

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<table>
<thead>
<tr>
<th>griseofulvin 500 mg tablet, 28</th>
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<tbody>
<tr>
<td>2982Y</td>
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</tr>
</tbody>
</table>

**TERBINAFINE**

**Authority required**
Treatment of a dermatophyte infection in an Aboriginal or a Torres Strait Islander person where topical treatment has failed

**Authority required**
Treatment of a dermatophyte infection in a patient aged up to 18 years inclusive where topical treatment and griseofulvin have failed
### TERBINAFINE

**Authority required**

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.

**Note**

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

### ANTIPSORIATICS

#### ANTIPSORIATICS FOR TOPICAL USE

### COAL TAR PREPARED

**Coal tar prepared 1% (10 mg/g) lotion, 100 mL**

**Other antipsorotics for topical use**

### CALCIPOTRIOL + BETAMETHASONE DIPROPIONATE

**Authority required**

Chronic stable plaque type psoriasis vulgaris

**Clinical criteria:**

The condition must be on the patient's scalp. AND

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.

**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:

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.

---

**calcipotriol 0.005% + betamethasone (as dipropionate) 0.05% gel, 30 g**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>†1</td>
<td>1</td>
<td>..</td>
<td>42.23</td>
<td>37.70</td>
<td>Daivobet 50/500 gel [LO]</td>
</tr>
</tbody>
</table>

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**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.

---

**calcipotriol 0.005% + betamethasone (as dipropionate) 0.05% ointment, 30 g**

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<tr>
<td>†1</td>
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<td>42.23</td>
<td>37.70</td>
<td>Daivobet [LO]</td>
</tr>
</tbody>
</table>

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**ANTIPSORIATICS FOR SYSTEMIC USE**

**Retinoids for treatment of psoriasis**

---

**ACITRETIN**

**Caution**

This drug is a potent teratogen—pregnancy should be avoided for at least two years after cessation of therapy.

**Authority required (STREAMLINED)**

1366

Severe intractable psoriasis

**Authority required (STREAMLINED)**

1363

Severe forms of disorders of keratinisation

**Note**

Care must be taken to comply with the provisions of State/Territory law when prescribing acitretin.

---

**acitretin 10 mg capsule, 100**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>2019G</td>
<td>1</td>
<td>2</td>
<td>..</td>
<td>174.32</td>
<td>* Acitretin Actavis [GN]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Neotigason [UA]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Novatin [TX]</td>
</tr>
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**acitretin 25 mg capsule, 100**

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<td>* Neotigason [UA]</td>
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<td></td>
<td></td>
<td>* Novatin [TX]</td>
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**ANTIBIOTICS AND CHEMOTHERAPEUTICS FOR DERMATOLOGICAL USE**

**CHEMOTHERAPEUTICS FOR TOPICAL USE**

**Sulfonamides**

---

**SULFADIAZINE SILVER**

**Restricted benefit**

Prevention and treatment of infection in partial or full skin thickness loss due to burns

**Restricted benefit**

Prevention and treatment of infection in partial or full skin thickness loss due to epidermolysis bullosa

**Restricted benefit**

Stasis ulcers
### HYDROCORTISONE ACETATE

**Restricted benefit**

Corticosteroid-responsive dermatoses

<table>
<thead>
<tr>
<th>Drug Description</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hydrocortisone acetate 1% (10 mg/g) cream, 30 g</td>
<td>Cortic-DS 1% [FM]</td>
</tr>
<tr>
<td>Hydrocortisone acetate 1% (10 mg/g) cream, 50 g</td>
<td>Cortic-DS 1% [FM]</td>
</tr>
<tr>
<td>Hydrocortisone acetate 1% (10 mg/g) ointment, 30 g</td>
<td>Cortic-DS 1% [FM]</td>
</tr>
<tr>
<td>Hydrocortisone acetate 1% (10 mg/g) ointment, 50 g</td>
<td>Cortic-DS 1% [FM]</td>
</tr>
</tbody>
</table>

### TRIAMCINOLONE

**Restricted benefit**

Treatment of corticosteroid-responsive dermatoses

<table>
<thead>
<tr>
<th>Drug Description</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Triamcinolone acetonide 0.02% (200 microgram/g) cream, 100 g</td>
<td>Tricortone [FM]</td>
</tr>
</tbody>
</table>

---

**General**

- ** sulfadiazine silver 1% (10 mg/g) cream, 50 g**
  - 9479X
  - †1 19.49 20.64 Flamazine [SN]
**DERMATOLOGICALS**

**Schedule of Pharmaceutical Benefits**

**General**

**triamcinolone acetonide 0.02% (200 microgram/g) ointment, 100 g**

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Premium $</th>
<th>DPMQ</th>
<th>MRVSN</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tricortone [FM]</td>
<td>14.74</td>
<td>15.89</td>
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</tr>
<tr>
<td>Anstocort 0.02% [QA]</td>
<td>18.52</td>
<td>15.89</td>
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</tr>
</tbody>
</table>

**Corticosteroids, potent (group III)**

**BETAMETHASONE DIPROPIONATE**

*Restricted benefit*

*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.

**betamethasone (as dipropionate) 0.05% cream, 15 g**

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Premium $</th>
<th>DPMQ</th>
<th>MRVSN</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eleuphrat [FR]</td>
<td>13.48</td>
<td>14.63</td>
<td></td>
</tr>
<tr>
<td>Diprosone [MK]</td>
<td>15.93</td>
<td>14.63</td>
<td></td>
</tr>
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</table>

**betamethasone (as dipropionate) 0.05% ointment, 15 g**

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Premium $</th>
<th>DPMQ</th>
<th>MRVSN</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eleuphrat [FR]</td>
<td>13.48</td>
<td>14.63</td>
<td></td>
</tr>
<tr>
<td>Diprosone [MK]</td>
<td>15.93</td>
<td>14.63</td>
<td></td>
</tr>
</tbody>
</table>

**BETAMETHASONE VALERATE**

*Restricted benefit*

*Corticosteroid-responsive dermatoses*

**betamethasone (as valerate) 0.02% (200 microgram/g) cream, 100 g**

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Premium $</th>
<th>DPMQ</th>
<th>MRVSN</th>
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<tbody>
<tr>
<td>Antroquoril [FR]</td>
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<tr>
<td>Betnovate 1/5 [QA]</td>
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<td>25.71</td>
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</tr>
</tbody>
</table>

**betamethasone (as valerate) 0.05% (500 microgram/g) cream, 15 g**

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Premium $</th>
<th>DPMQ</th>
<th>MRVSN</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cortival 1/2 [FM]</td>
<td>24.66</td>
<td>25.71</td>
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<tr>
<td>Celestone-M [MK]</td>
<td>27.02</td>
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</table>

**BETAMETHASONE VALERATE**

*Restricted benefit*

*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.

**betamethasone (as valerate) 0.05% (500 microgram/g) ointment, 15 g**

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Premium $</th>
<th>DPMQ</th>
<th>MRVSN</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cortival 1/2 [FM]</td>
<td>24.66</td>
<td>25.71</td>
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<tr>
<td>Betnovate 1/2 [QA]</td>
<td>27.02</td>
<td>25.71</td>
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</tr>
</tbody>
</table>

**METHYLPREDNISOLONE**

*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.

**methyldapridnisolone aceponate 0.1% (1 mg/g) cream, 15 g**

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Premium $</th>
<th>DPMQ</th>
<th>MRVSN</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cortival 1/2 [FM]</td>
<td>14.32</td>
<td>15.47</td>
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</tr>
</tbody>
</table>

**methyldapridnisolone aceponate 0.1% (1 mg/g) ointment, 15 g**

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Premium $</th>
<th>DPMQ</th>
<th>MRVSN</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cortival 1/2 [FM]</td>
<td>14.32</td>
<td>15.47</td>
<td></td>
</tr>
</tbody>
</table>
**DERMATOLOGICALS**

**methylprednisolone aceponate 0.1% (1 mg/g) ointment, 15 g**

<table>
<thead>
<tr>
<th>Max.Qty</th>
<th>Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMO $</th>
<th>MRVSN $</th>
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</tr>
</thead>
<tbody>
<tr>
<td>†1</td>
<td>..</td>
<td>..</td>
<td>14.32</td>
<td>15.47</td>
<td></td>
<td>Advantan [BN]</td>
</tr>
</tbody>
</table>

**METHYLPREDNISOLONE**

**Restricted benefit**

| Eczema |

**Note**

Continuing Therapy Only:

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

**methylprednisolone aceponate 0.1% (1 mg/g) lotion, 20 g**

<table>
<thead>
<tr>
<th>Max.Qty</th>
<th>Packs</th>
<th>No. of Rpts</th>
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<th>DPMO $</th>
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<tbody>
<tr>
<td>†1</td>
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<td>14.99</td>
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<td>Advantan [BN]</td>
</tr>
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</table>

**MOMETASONE**

**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.

**mometasone furoate 0.1% (1 mg/g) cream, 15 g**

<table>
<thead>
<tr>
<th>Max.Qty</th>
<th>Packs</th>
<th>No. of Rpts</th>
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<th>DPMO $</th>
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<tr>
<td>†1</td>
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<td>..</td>
<td>12.35</td>
<td>13.50</td>
<td>* Mamasone [QA]</td>
<td>* Novasone [FR]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>3.07</td>
<td>15.42</td>
<td>13.50</td>
<td>* Elocon [MK]</td>
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</table>

**mometasone furoate 0.1% lotion, 30 mL**

<table>
<thead>
<tr>
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<th>Packs</th>
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<tbody>
<tr>
<td>†1</td>
<td>..</td>
<td>..</td>
<td>15.58</td>
<td>16.73</td>
<td>* Novasone [FR]</td>
<td>* Zatamil [EO]</td>
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<td></td>
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<td>3.06</td>
<td>18.64</td>
<td>16.73</td>
<td>* Elocon [MK]</td>
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**mometasone furoate 0.1% ointment, 15 g**

<table>
<thead>
<tr>
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<td>13.50</td>
<td>* Novasone [FR]</td>
<td>* Zatamil [EO]</td>
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<td>3.07</td>
<td>15.42</td>
<td>13.50</td>
<td>* Elocon [MK]</td>
</tr>
</tbody>
</table>

**Corticosteroids, very potent (group IV)**

**CLOBETASOL**

**Authority required**

Moderate to severe scalp psoriasis

**Clinical criteria:**

The condition must be inadequately controlled with either a vitamin D analogue or potent topical corticosteroid as monotherapy; OR

The condition must be inadequately controlled with combination use of a vitamin D analogue and potent topical corticosteroid.

**Population criteria:**

Patient must be aged 18 years or older.

**clobetasol propionate 0.05% shampoo, 125 mL**

<table>
<thead>
<tr>
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<th>DPMO $</th>
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<td>48.98</td>
<td>37.70</td>
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</table>

**ANTI-ACNE PREPARATIONS**

**ANTI-ACNE PREPARATIONS FOR TOPICAL USE**

**Retinoids for topical use in acne**

**ADAPALENE + BENZOYL PEROXIDE**

**Restricted benefit**

Severe acne vulgaris

Treatment Phase: Acute treatment
Clinical criteria:
The treatment must in combination with an oral antibiotic.

adapalene 0.1% + benzoyl peroxide 2.5% gel, 30 g

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>‡1</td>
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<td>..</td>
<td>37.27</td>
<td>37.70</td>
<td>Epiduo [GA]</td>
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</tbody>
</table>

**ADAPALENE + BENZOYL PEROXIDE**

**Restricted benefit**
Severe acne vulgaris

**Clinical criteria:**
The treatment must be maintenance therapy.

**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.

adapalene 0.1% + benzoyl peroxide 2.5% gel, 30 g

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>‡1</td>
<td>3</td>
<td>..</td>
<td>37.27</td>
<td>37.70</td>
<td>Epiduo [GA]</td>
</tr>
</tbody>
</table>

**ANTI-ACNE PREPARATIONS FOR SYSTEMIC USE**

**Retinoids for treatment of acne**

**ISOTRETINOIN**

**Caution**
This drug causes birth defects. Isotretinoin has been reported to cause other frequent and potentially serious toxicity.

**Authority required (STREAMLINED)**

1354
Severe cystic acne not responsive to other therapy

**Note**
Care must be taken to comply with the provisions of State/Territory law when prescribing isotretinoin.

isotretinoin 10 mg capsule, 60

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<td>2591J</td>
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<td>3</td>
<td>..</td>
<td>43.29</td>
<td>isotretinoin AN [EA]</td>
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</table>

isotretinoin 20 mg capsule, 60

<table>
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<tr>
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<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
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isotretinoin 40 mg capsule, 30

<table>
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<th>DPMQ $</th>
<th>MRVSN $</th>
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<td>56.32</td>
<td>isotretinoin AN [EA]</td>
</tr>
</tbody>
</table>

**OTHER DERMATOLOGICAL PREPARATIONS**

**OTHER DERMATOLOGICAL PREPARATIONS**

**Agents for dermatitis, excluding corticosteroids**

**PIMECROLIMUS**

**Authority required**
Treatment of facial or eyelid atopic dermatitis in patients aged at least 3 months with 1 or more of the following contraindications to topical corticosteroids:
(i) perioral dermatitis;
(ii) periorbital dermatitis;
(iii) rosacea;
(iv) epidermal atrophy;
(v) dermal atrophy;
(vi) allergy to topical corticosteroids;
(vii) cataracts;
(viii) glaucoma;
(ix) raised intraocular pressure

**Authority required**

Short-term (up to 3 weeks) intermittent treatment of atopic dermatitis of the face or eyelids in patients aged at least 3 months who fail to achieve satisfactory disease control with intermittent topical corticosteroid therapy, and where more than 3 months have passed since the initial diagnosis of atopic dermatitis.

Failure to achieve satisfactory disease control with intermittent topical corticosteroid therapy is manifest by:

(i) failure of the facial skin to clear despite at least 2 weeks of topical hydrocortisone 1% applied every day; or

(ii) failure of the facial skin to clear despite at least 1 week of a moderate or potent topical corticosteroid applied every day; or

(iii) clearing of the facial skin with at least 2 weeks of topical hydrocortisone 1% applied every day, but almost immediate and significant flare in facial disease (within 48 hours) upon stopping topical corticosteroids, occurring on at least 2 consecutive occasions; or

(iv) clearing of the facial skin with at least 1 week of a moderate or potent topical corticosteroid applied every day, but almost immediate and significant flare in facial disease (within 48 hours) upon stopping topical corticosteroids, occurring on at least 2 consecutive occasions

**Note**

No applications for increased maximum quantities and/or repeats will be authorised. Only 1 authority application per 6 months, per patient, will be authorised.

### pimecrolimus 1% (10 mg/g) cream, 15 g

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>1</td>
<td>..</td>
<td>34.13</td>
<td>35.28</td>
<td>Elidel [HM]</td>
</tr>
</tbody>
</table>

### 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.

### 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.

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

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

Treatment of recurrent (previously treated) lesions will not be authorised.

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.

### imiquimod 5% cream, 12 x 250 mg sachets

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>1</td>
<td>..</td>
<td>135.72</td>
<td>37.70</td>
<td>*Aldara [IA]</td>
</tr>
</tbody>
</table>

* Aldiq [QA]
imiquimod 5% cream, 2 x 2 g pump packs

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
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<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>1</td>
<td>1</td>
<td>..</td>
<td>135.72</td>
<td>37.70</td>
<td>* Aldara Pump [IA]</td>
</tr>
</tbody>
</table>

**GENITO URINARY SYSTEM AND SEX HORMONES**

**OTHER GYNECOLOGICALS**

**CONTRACEPTIVES FOR TOPICAL USE**

*Intrauterine contraceptives*

**LEVONORGESTREL**

- Restricted benefit
- Contraception

*Restricted benefit*

- Idiopathic menorrhagia where oral treatments are ineffective
- Idiopathic menorrhagia where oral treatments are contraindicated

**leovonorgestrel 52 mg drug delivery system: intrauterine, 1 system**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
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<tr>
<td>8633J</td>
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<td>..</td>
<td>266.56</td>
<td>37.70</td>
<td>Mirena [BN]</td>
</tr>
</tbody>
</table>

**OTHER GYNECOLOGICALS**

*Prolactine inhibitors*

**BROMOCRIPTINE**

- Restricted benefit
- Prevention of the onset of lactation in the puerperium for medical reasons

**bromocriptine 2.5 mg tablet, 30**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
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<tr>
<td>1444B</td>
<td>..</td>
<td>..</td>
<td>19.26</td>
<td>20.41</td>
<td>* Kripton 2.5 [AF]</td>
</tr>
</tbody>
</table>

**BROMOCRIPTINE**

- Restricted benefit
- Acromegaly
- Parkinson's disease
- 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.

For item codes 1443Y and 1559C, pharmaceutical benefits that have the form tablet 2.5 mg (base) are equivalent for the purposes of substitution.

**bromocriptine 2.5 mg tablet, 30**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
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<tr>
<td>1443Y</td>
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<td>31.76</td>
<td>32.91</td>
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**bromocriptine 2.5 mg tablet, 60**

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<tr>
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<td>31.76</td>
<td>32.91</td>
<td>* Kripton 2.5 [AF]</td>
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**CABERGOLINE**

- Restricted benefit
- Prevention of the onset of lactation in the puerperium for medical reasons
cabergoline 500 microgram tablet, 2

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<td>Dostinex [PF]</td>
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**Quinagolide**

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<tr>
<td>2659 Pathological hyperprolactinaemia where surgery is not indicated</td>
</tr>
<tr>
<td>2660 Pathological hyperprolactinaemia where surgery has already been used with incomplete resolution</td>
</tr>
<tr>
<td>2661 Pathological hyperprolactinaemia where radiotherapy is not indicated</td>
</tr>
<tr>
<td>2662 Pathological hyperprolactinaemia where radiotherapy has already been used with incomplete resolution</td>
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quinagolide 25 microgram tablet [3 tablets] (&) quinagolide 50 microgram tablet [3 tablets], 6

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quinagolide 75 microgram tablet, 30

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**Sex Hormones and Modulators of the Genital System**

**Hormonal Contraceptives for Systemic Use**

**Progestogens and estrogens, fixed combinations**

**Ethinyloestradiol + Levonorgestrel**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
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<td>1</td>
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### GENITO URINARY SYSTEM AND SEX HORMONES

#### ETHINYL Estradiol + Norethisterone

<table>
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<th>Schedule</th>
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<tbody>
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<td>2416E</td>
<td>Femme-Tab ED 20/100 [AE]</td>
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#### Ethinyl Estradiol 35 microgram + Norethisterone 1 mg tablet [84] (&) inert substance tablet [28], 112 [4 x 28]

<table>
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<td>Norimin-1 28 Day [FZ]</td>
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<td>2774B</td>
<td>Brevinor [PF]</td>
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#### Mestranol + Norethisterone

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<tbody>
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<td>3179H</td>
<td>Norinyl-1/28 [PF]</td>
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#### Progestogens and Estrogens, Sequential Preparations

#### Ethinyl Estradiol + Levonorgestrel

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<td>Logynon ED [SY]</td>
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<td></td>
<td>Triquilar ED [BN]</td>
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#### Progestogens

#### Etonogestrel

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#### Levonorgestrel

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#### Medroxyprogesterone

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<td>Depo-Provera [PF]</td>
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#### Norlethisterone

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<td>Micronor [JC]</td>
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<td></td>
<td>Noriday 28 Day [PF]</td>
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### ANDROGENS

#### 3-oxoandrostene (4) derivatives

#### Testosterone

**Authority required**

Androgen deficiency

Clinical criteria:
Patient must have an established pituitary or testicular disorder.

**Population criteria:**
Patient must be male.

**Treatment criteria:**
Must be treated by a specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a registered member of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

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

**Authority required**

**Androgen deficiency**

**Clinical criteria:**
Patient must not have an established pituitary or testicular disorder, AND

The condition must not be due to age, obesity, cardiovascular diseases, infertility or drugs.

**Population criteria:**
Patient must be male, AND

Patient must be aged 40 years or older.

**Treatment criteria:**
Must be treated by a specialist urologist, specialist endocrinologist or a registered member of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

Androgen deficiency is defined as:
(i) testosterone level of less than 6 nmol per litre; OR
(ii) testosterone level between 6 and 15 nmol per litre with high luteinising hormone (LH) (greater than 1.5 times the upper limit of the eugonodal reference range for young men, or greater than 14 IU per litre, whichever is higher).

Androgen deficiency must be confirmed by at least two morning blood samples taken on different mornings.

The dates and levels of the qualifying testosterone and LH measurements must be, or must have been provided in the authority application when treatment with this drug is or was initiated.

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

**Micropenis**

**Population criteria:**
Patient must be male, AND

Patient must be under 18 years of age.

**Treatment criteria:**
Must be treated by a specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a registered member of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

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

**Pubertal induction**

**Population criteria:**
Patient must be male, AND

Patient must be under 18 years of age.

**Treatment criteria:**
Must be treated by a specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a registered member of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

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

**Constitutional delay of growth or puberty**

**Population criteria:**
Patient must be male, AND

Patient must be under 18 years of age.

**Treatment criteria:**
Must be treated by a specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a registered member of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

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

---

### Testosterone 1% (50 mg/5 g) Gel, 30 x 5 g Sachets

<table>
<thead>
<tr>
<th>Testosterone 1% (50 mg/5 g) gel, 30 x 5 g sachets</th>
</tr>
</thead>
<tbody>
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<td><strong>Brand Name and Manufacturer</strong></td>
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<td><strong>Testogel [HB]</strong></td>
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<tr>
<td><strong>Max Qty Packs</strong></td>
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<td>8830R</td>
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### Testosterone 2% (30 mg/1.5 mL Actuation) Transdermal Solution, 60 Actuations

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<th>Testosterone 2% (30 mg/1.5 mL actuation) transdermal solution, 60 actuations</th>
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<tbody>
<tr>
<td><strong>Brand Name and Manufacturer</strong></td>
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<tr>
<td><strong>Axiron [LY]</strong></td>
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<tr>
<td><strong>Max Qty Packs</strong></td>
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<td>2341F</td>
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</table>
testosterone 2.5 mg/24 hours patch, 60

<table>
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<th>DPMO $</th>
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<tbody>
<tr>
<td>‡1</td>
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<td>96.18</td>
<td>37.70</td>
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8460G

testosterone 5 mg/24 hours patch, 30

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<td>‡1</td>
<td>5</td>
<td>..</td>
<td>96.18</td>
<td>37.70</td>
<td>Androderm [GN]</td>
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</tbody>
</table>

8619P

=TETOSTERONE ENANTHATE=

**Authority required**
Androgen deficiency

**Clinical criteria:**
Patient must have an established pituitary or testicular disorder.

**Population criteria:**
Patient must be male.

**Treatment criteria:**
Must be treated by a specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a registered member of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

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

**Authority required**
Androgen deficiency

**Clinical criteria:**
Patient must not have an established pituitary or testicular disorder, AND

The condition must not be due to age, obesity, cardiovascular diseases, infertility or drugs.

**Population criteria:**
Patient must be male, AND

Patient must be aged 40 years or older.

**Treatment criteria:**
Must be treated by a specialist urologist, specialist endocrinologist or a registered member of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

Androgen deficiency is defined as:

(i) testosterone level of less than 6 nmol per litre; OR

(ii) testosterone level between 6 and 15 nmol per litre with high luteinising hormone (LH) (greater than 1.5 times the upper limit of the eugonodal reference range for young men, or greater than 14 IU per litre, whichever is higher).

Androgen deficiency must be confirmed by at least two morning blood samples taken on different mornings.

The dates and levels of the qualifying testosterone and LH measurements must be, or must have been provided in the authority application when treatment with this drug is or was initiated.

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

**Authority required**
Micropenis

**Population criteria:**
Patient must be male, AND

Patient must be under 18 years of age.

**Treatment criteria:**
Must be treated by a specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a registered member of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

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

**Authority required**
Pubertal induction

**Population criteria:**
Patient must be male, AND

Patient must be under 18 years of age.

**Treatment criteria:**
Must be treated by a specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a registered member of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

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

**Authority required**
Constitutional delay of growth or puberty

**Population criteria:**
Patient must be male, AND

Patient must be under 18 years of age.

**Treatment criteria:**
Must be treated by a specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a registered member of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

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

**testosterone enanthate 250 mg/mL injection, 3 x 1 mL syringes**

<table>
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<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
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<td>33.82</td>
<td>34.97</td>
<td>Primoteston Depot [BN]</td>
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### TESTOSTERONE UNDECANOATE

**Authority required**

Androgen deficiency

**Clinical criteria:**

Patient must have an established pituitary or testicular disorder.

**Population criteria:**

Patient must be male.

**Treatment criteria:**

Must be treated by a specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a registered member of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

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

**Testosterone unadjusted**

**Population criteria:**

Patient must have an established pituitary or testicular disorder, AND

The condition must not be due to age, obesity, cardiovascular diseases, infertility or drugs.

**Treatment criteria:**

Must be treated by a specialist urologist, specialist endocrinologist or a registered member of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

**Authority required**

Androgen deficiency

**Clinical criteria:**

Patient must have an established pituitary or testicular disorder, AND

The condition must not be due to age, obesity, cardiovascular diseases, infertility or drugs.

**Population criteria:**

Patient must be male, AND

Patient must be aged 40 years or older.

**Treatment criteria:**

Must be treated by a specialist urologist, specialist endocrinologist or a registered member of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

Androgen deficiency is defined as:

(i) testosterone level of less than 6 nmol per litre; OR

(ii) testosterone level between 6 and 15 nmol per litre with high luteinising hormone (LH) (greater than 1.5 times the upper limit of the eugonodal reference range for young men, or greater than 14 IU per litre, whichever is higher).

Androgen deficiency must be confirmed by at least two morning blood samples taken on different mornings.

The dates and levels of the qualifying testosterone and LH measurements must be, or must have been provided in the authority application when treatment with this drug is or was initiated.

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

**Authority required**

Micropenis

**Population criteria:**

Patient must be male, AND

Patient must be under 18 years of age.

**Treatment criteria:**

Must be treated by a specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a registered member of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

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

**Authority required**

Pubertal induction

**Population criteria:**

Patient must be male, AND

Patient must be under 18 years of age.

**Treatment criteria:**

Must be treated by a specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a registered member of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

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

**Authority required**

Constitutional delay of growth or puberty

**Population criteria:**

Patient must be male, AND

Patient must be under 18 years of age.

**Treatment criteria:**
GENITO URINARY SYSTEM AND SEX HORMONES

Must be treated by a specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a registered member of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.
The name of the specialist must be included in the authority application.

**testosterone undecanoate 1 g/4 mL injection, 1 x 4 mL vial**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
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<th>DPMQ $</th>
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<td>147.75</td>
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**testosterone undecanoate 40 g capsule, 60**

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**ESTROGENS**

_Natural and semisynthetic estrogens, plain_

### OESTRADIOL

**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.

**oestradiol 10 microgram pessary: modified release, 18**

<table>
<thead>
<tr>
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### OESTRADIOL

**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.

**oestradiol 2 mg tablet, 56**

<table>
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<td>8274L</td>
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<td></td>
<td>13.89</td>
<td>15.04</td>
<td>Zumenon [GO]</td>
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</table>

**oestradiol valerate 1 mg tablet, 56**

<table>
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<th>Max Qty Packs</th>
<th>No. of Rpts</th>
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<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tr>
<td>1663M</td>
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<td>12.02</td>
<td>13.17</td>
<td>Progynova [BN]</td>
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**oestradiol valerate 2 mg tablet, 56**

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<td>14.24</td>
<td>15.39</td>
<td>Progynova [BN]</td>
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</tbody>
</table>

### OESTRADIOL

**Note**

Oestradiol should be used in conjunction with an oral progestogen in women with an intact uterus.

**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.

**oestradiol 0.1% (1 mg/g) gel, 28 x 1 g sachets**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>8266D</td>
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<td></td>
<td>17.43</td>
<td>18.58</td>
<td>Sandrena [AS]</td>
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**oestradiol 100 microgram/24 hours patch, 4**

<table>
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<th>Premium $</th>
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<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
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<td>8126Q</td>
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<td>19.47</td>
<td>20.62</td>
<td>Climara 100 [BN]</td>
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</tbody>
</table>

**oestradiol 100 microgram/24 hours patch, 8**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<td>8312L</td>
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<td>19.47</td>
<td>20.62</td>
<td>Estraderm MX 100 [NV]</td>
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</tbody>
</table>
oestradiol 100 microgram/24 hours patch, 8
8765H
Max Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer
†1 5 .. 19.47 20.62 Estradot 100 [NV]

oestradiol 25 microgram/24 hours patch, 4
8485N
Max Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer
†1 5 .. 17.43 18.58 Climara 25 [BN]

oestradiol 25 microgram/24 hours patch, 8
8311K
Max Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer
†1 5 .. 17.43 18.58 Estraderm MX 25 [NV]

oestradiol 25 microgram/24 hours patch, 8
8761D
Max Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer
†1 5 .. 17.43 18.58 Estradot 25 [NV]

oestradiol 37.5 microgram/24 hours patch, 8
8762E
Max Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer
†1 5 .. 17.43 18.58 Estradot 37.5 [NV]

oestradiol 50 microgram/24 hours patch, 4
8125P
Max Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer
†1 5 .. 17.43 18.58 Climara 50 [BN]

oestradiol 50 microgram/24 hours patch, 8
8140K
Max Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer
†1 5 .. 17.43 18.58 Estraderm MX 50 [NV]

oestradiol 50 microgram/24 hours patch, 8
8763F
Max Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer
†1 5 .. 17.43 18.58 Estradot 50 [NV]

oestradiol 75 microgram/24 hours patch, 4
8486P
Max Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer
†1 5 .. 19.47 20.62 Climara 75 [BN]

oestradiol 75 microgram/24 hours patch, 8
8764G
Max Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer
†1 5 .. 19.47 20.62 Estradot 75 [NV]

OESTRIOL

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.

oestradiol 0.1% (1 mg/g) cream, 15 g
1781R
Max Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer
†1 1 .. 19.43 20.58 Ovestin [AS]

oestradiol 500 microgram pessary, 15
1771F
Max Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer
†1 2 .. 21.60 22.75 Ovestin Ovula [AS]

PROGESTOGENS
Pregnen (4) derivatives

MEDRXYPROGESTERONE

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.
### Genito Urinary System and Sex Hormones

**Medroxyprogesterone acetate 10 mg tablet, 30**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>1</td>
<td>2</td>
<td></td>
<td>14.66</td>
<td>15.81</td>
<td>* Ralovera [FZ]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>2.46</td>
<td>17.12</td>
<td>* Provera [PF]</td>
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</table>

**Medroxyprogesterone acetate 5 mg tablet, 56**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>2</td>
<td></td>
<td>15.96</td>
<td>17.11</td>
<td>* Ralovera [FZ]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>2.59</td>
<td>18.55</td>
<td>* Provera [PF]</td>
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</table>

**Medroxyprogesterone**

*Restricted benefit*

**Endometriosis**

**Medroxyprogesterone acetate 10 mg tablet, 100**

<table>
<thead>
<tr>
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<th>No. of Rpts</th>
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<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
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<tr>
<td>1</td>
<td>2</td>
<td></td>
<td>33.10</td>
<td>34.25</td>
<td>* Ralovera [FZ]</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>2.53</td>
<td>35.63</td>
<td>* Provera [PF]</td>
</tr>
</tbody>
</table>

**Estren derivatives**

**Norethisterone**

*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.

**Norethisterone 5 mg tablet, 30**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
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<td>2</td>
<td></td>
<td>32.30</td>
<td>33.45</td>
<td>Primolut N [BN]</td>
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</table>

**Progestogens and Estrogens in Combination**

**Progestogens and estrogens, fixed combinations**

**Norethisterone acetate + Oestradiol**

*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.

**Oestradiol 50 microgram/24 hours + norethisterone acetate 140 microgram/24 hours patch, 8**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>‡1</td>
<td>5</td>
<td></td>
<td>19.47</td>
<td>20.62</td>
<td>Estalis continuous 50/140 [NV]</td>
</tr>
</tbody>
</table>

**Oestradiol 50 microgram/24 hours + norethisterone acetate 250 microgram/24 hours patch, 8**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
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<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>‡1</td>
<td>5</td>
<td></td>
<td>19.47</td>
<td>20.62</td>
<td>Estalis continuous 50/250 [NV]</td>
</tr>
</tbody>
</table>

**Oestradiol + Dydrogesterone**

*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.

**Oestradiol 1 mg + dydrogesterone 5 mg tablet, 28**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>5</td>
<td></td>
<td>19.10</td>
<td>20.25</td>
<td>Femoston-Conti [GO]</td>
</tr>
</tbody>
</table>

**Progesterogens and estrogens, sequential preparations**

**Norethisterone acetate + Oestradiol ( &) Oestradiol**

*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.

### OESTRADIOL (&) OESTRADIOL + NORETHISTERONE

#### 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.

### OESTRADIOL (&) OESTRADIOL + DydROGesterone

#### 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.
follitropin alfa 900 international units / 1.5 mL (65.52 microgram/1.5 mL) injection, 1 x 1.5 mL cartridge

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
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<tr>
<td>8715Q</td>
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<td>5</td>
<td>..</td>
<td>980.94</td>
<td>Gonal-f Pen [SG]</td>
</tr>
</tbody>
</table>

- **FOLLITROPIN BETA**
  - **Restricted benefit**
  - Anovulatory infertility

  For the treatment of infertility in males due to hypogonadotrophic hypogonadism, following failure of 6 months' treatment with human chorionic gonadotrophin to achieve adequate spermatogenesis. Combined treatment with HCG must be given.

  **Note**
  - Except in cases of hypopituitarism or primary amenorrhoea, the patient should have been adequately treated with clomiphene citrate and/or gonadorelin and failed to have conceived.
  - Women who have had apparent ovulation induced by other agents and have failed to conceive should have laparoscopic evidence that there is no other impediment to conception.
  - Oligomenorrhoea should have been present for at least twelve months or amenorrhoea for at least six months prior to treatment.

  Patients with hyperprolactinaemia should have had appropriate surgical or medical treatment prior to treatment.

- **FOLLITROPIN BETA**
  - **Restricted benefit**
  - Anovulatory infertility

  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.

- **GONADOTROPHIN CHORIONIC HUMAN**
  - **Restricted benefit**
  - Anovulatory infertility

  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.

- **CLOMIPHENE**
  - **Restricted benefit**
  - Anovulatory infertility

  For the treatment of infertility in females due to isolated ovulatory dysfunction.
Patients undergoing in-vitro fertilisation

Note
Care must be taken to comply with the provisions of State/Territory law when prescribing clomiphene citrate.

clophimene citrate 50 mg tablet, 10

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
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<tr>
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<td>..</td>
<td>34.85</td>
<td>36.00</td>
<td>* Clomid [SW]</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Serophene [SG]</td>
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</table>

ANTIANDROGENS
Antiandrogens, plain

- CYPROTERONE

Caution
This drug should not be used during pregnancy as it may result in feminisation of the male foetus.

Authority required (STREAMLINED)

1230
Moderate to severe androgenisation in non-pregnant women (acne alone is not a sufficient indication of androgenisation)

cyproterone acetate 50 mg tablet, 20

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
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<th>DPMQ $</th>
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<td>27.79</td>
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<td>* Cyprocur 50 [QA]</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Cyprostone [SY]</td>
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<tr>
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<td></td>
<td></td>
<td></td>
<td>* Cyproterone Sandoz [HX]</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Procur [GN]</td>
</tr>
<tr>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>* Cyproterone AN [EA]</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* GenRx Cyproterone Acetate [GX]</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Androcur [BN]</td>
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</table>

- CYPROTERONE

Authority required (STREAMLINED)

1014
Advanced carcinoma of the prostate

Authority required (STREAMLINED)

1404
To reduce drive in sexual deviations in males

cyproterone acetate 100 mg tablet, 50

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
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<tr>
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<td>..</td>
<td>85.11</td>
<td>37.70</td>
<td>* Cyprocur 100 [QA]</td>
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<td></td>
<td>* Cyproterone AN [EA]</td>
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<tr>
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<td>* GenRx Cyproterone Acetate [GX]</td>
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<td></td>
<td></td>
<td></td>
<td>* Cyproterone Sandoz [HX]</td>
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<td></td>
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<td></td>
<td>* Cyproterone Sandoz [HX]</td>
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<td>* Procur [GN]</td>
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<td></td>
<td>* Androcur-100 [BN]</td>
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</table>

- CYPROTERONE

Authority required (STREAMLINED)

1270W
Moderate to severe androgenisation in non-pregnant women (acne alone is not a sufficient indication of androgenisation)

cyproterone acetate 50 mg tablet, 50

<table>
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<th>Premium $</th>
<th>DPMQ $</th>
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<td>..</td>
<td>107.36</td>
<td>37.70</td>
<td>* Cyprocur 50 [QA]</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>* Procur [GN]</td>
</tr>
</tbody>
</table>

OTHER SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM
Antagonadotropins and similar agents

- DANAZOL

Caution
Pregnancy must be excluded prior to administration of this drug.

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)

danazol 100 mg capsule, 100

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>1285P</td>
<td>5</td>
<td>58.92</td>
<td>37.70</td>
<td>Azol 100 [AF]</td>
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</table>

danazol 200 mg capsule, 100

<table>
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<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>1287R</td>
<td>5</td>
<td>87.31</td>
<td>37.70</td>
<td>Azol 200 [AF]</td>
<td></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)

gestrinone 2.5 mg capsule, 8

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
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<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>8015W</td>
<td>5</td>
<td>82.15</td>
<td>37.70</td>
<td>Dimetriose [SW]</td>
<td></td>
</tr>
</tbody>
</table>

Progesterone receptor modulators

MIFEPRISTONE (&) MISOPROSTOL

Authority required
Termination of an intra-uterine pregnancy

Clinical criteria:
The condition must be an intra-uterine pregnancy of up to 63 days of gestation.

Treatment criteria:
Must be treated by a prescriber who is registered with the MS 2 Step Prescribing Program.

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

mifepristone 200 mg tablet [1] (&) misoprostol 200 microgram tablet [4], 1 pack

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
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<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>10211K</td>
<td>‡1</td>
<td>321.38</td>
<td>37.70</td>
<td>MS-2 Step [XH]</td>
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</table>

UROLOGICALS

Drugs for urinary frequency and incontinence

OXYBUTYNN

Restricted benefit
Detrusor overactivity

oxybutynin hydrochloride 5 mg tablet, 100

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
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<tbody>
<tr>
<td>8039D</td>
<td>5</td>
<td>13.80</td>
<td>14.95</td>
<td>* Ditropan [SW]</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Oxybutynin Sandoz [SZ]</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Oxybutynin Winthrop [WA]</td>
<td></td>
</tr>
</tbody>
</table>

OXYBUTYNN

Restricted benefit
Detrusor overactivity in a patient who cannot tolerate oral oxybutynin, or who cannot swallow oral oxybutynin

oxybutynin 3.9 mg/24 hours patch, 8

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
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<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>9454N</td>
<td>‡1</td>
<td>35.57</td>
<td>36.72</td>
<td>Oxytrol [GN]</td>
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</table>

PROPANTHILINE

Restricted benefit
Detrusor overactivity
propantheline bromide 15 mg tablet, 100

<table>
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<th>No. of Rpts</th>
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<tbody>
<tr>
<td>1953T</td>
<td>2</td>
<td>5</td>
<td>.</td>
<td>26.80</td>
<td>27.95 Pro-Banthine [QA]</td>
</tr>
</tbody>
</table>

Other urologicals

- **BICARBONATE**

  sodium bicarbonate 840 mg capsule, 100

<table>
<thead>
<tr>
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<tr>
<td>9470K</td>
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<td>14.34</td>
<td>15.49 Sodibic [AS]</td>
</tr>
</tbody>
</table>

- **PHENOXYBENZAMINE**

  Authority required
  Phaeochromocytoma
  Authority required
  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.

  phenoxybenzamine hydrochloride 10 mg capsule, 100

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
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<th>MRVSN $</th>
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<tbody>
<tr>
<td>1862B</td>
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<td>.</td>
<td>1164.81</td>
<td>37.70 Dibenzyline [GH]</td>
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<tr>
<td>9286R</td>
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<td>.</td>
<td>6860.58</td>
<td>37.70 Dibenzyline [BZ]</td>
</tr>
<tr>
<td>1166J</td>
<td>3</td>
<td>5</td>
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<td>*205.24</td>
<td>37.70 Dibenzyline [GH]</td>
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</tbody>
</table>

DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY

- **DUTASTERIDE + TAMSULOSIN**

  Authority required (STREAMLINED)
  3687
  Treatment of lower urinary tract symptoms due to benign prostatic hyperplasia where treatment has been initiated by a urologist

  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.

  dutasteride 500 microgram + tamsulosin hydrochloride 400 microgram capsule: modified release, 30

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
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<tbody>
<tr>
<td>5490Y</td>
<td>1</td>
<td>5</td>
<td>.</td>
<td>35.63</td>
<td>36.78 Duodart 500ug/400ug [GK]</td>
</tr>
</tbody>
</table>

- **DUTASTERIDE**

  Authority required (STREAMLINED)
  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

  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.
**SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS**

**PITUITARY AND HYPOTHALAMIC HORMONES AND ANALOGUES**

**ANTERIOR PITUITARY LOBE HORMONES AND ANALOGUES**

### ACTH

**TETRACOSACTRIN**

tetraicosactrin 1 mg/mL injection: modified release, 1 x 1 mL ampoule

<table>
<thead>
<tr>
<th>Max.Qty</th>
<th>Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>5</td>
<td></td>
<td>5</td>
<td>..</td>
<td>71.61</td>
<td>37.70</td>
<td>Synacthen Depot 1 mg/1 mL [NV]</td>
</tr>
</tbody>
</table>

**THYROTROPIN ALFA**

*Authority required (STREAMLINED)*

3193

Ablation of thyroid remnant tissue, in combination with radioactive iodine, in a post thyroidectomy patient without known metastatic disease

thyrotropin alfa 900 microgram injection, 2 x 900 microgram vials

<table>
<thead>
<tr>
<th>Max.Qty</th>
<th>Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
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<tr>
<td>1</td>
<td></td>
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<td>1901.76</td>
<td>37.70</td>
<td></td>
<td>Thyrogen [GZ]</td>
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</table>

**POSTERIOR PITUITARY LOBE HORMONES**

**Vasopressin and analogues**

**DESMOPRESSIN**

*Authority required (STREAMLINED)*

1678 Cranial diabetes insipidus

desmopressin acetate 10 microgram/actuation nasal spray, 60 actuations

<table>
<thead>
<tr>
<th>Max.Qty</th>
<th>Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>2</td>
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<td>5</td>
<td>*161.38</td>
<td>37.70</td>
<td></td>
<td>Minirin Nasal Spray [FP]</td>
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</tbody>
</table>

desmopressin acetate 100 microgram/mL nasal drops, 2.5 mL

<table>
<thead>
<tr>
<th>Max.Qty</th>
<th>Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>5</td>
<td></td>
<td>5</td>
<td>*161.51</td>
<td>37.70</td>
<td></td>
<td>Minirin [FP]</td>
</tr>
</tbody>
</table>

desmopressin acetate 200 microgram tablet, 30

<table>
<thead>
<tr>
<th>Max.Qty</th>
<th>Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>3</td>
<td></td>
<td>5</td>
<td>*180.25</td>
<td>37.70</td>
<td></td>
<td>Minirin [FP]</td>
</tr>
</tbody>
</table>

**DESMOPRESSIN**

*Authority required (STREAMLINED)*

2641 Primary nocturnal enuresis in patients aged 6 years or older who are refractory to an enuresis alarm

**Authority required (STREAMLINED)**

2642 Primary nocturnal enuresis in patients aged 6 years or older for whom an enuresis alarm is contraindicated. The reason that an alarm is contraindicated must be documented in the patient’s medical records when treatment is initiated

**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.

desmopressin acetate 10 microgram/actuation nasal spray, 60 actuations

<table>
<thead>
<tr>
<th>Max.Qty</th>
<th>Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>1‡</td>
<td></td>
<td>5</td>
<td>84.07</td>
<td>37.70</td>
<td></td>
<td>Minirin Nasal Spray [FP]</td>
</tr>
</tbody>
</table>

**DESMOPRESSIN**

*Authority required (STREAMLINED)*
Primary nocturnal enuresis in patients aged 6 years or older who are refractory to an enuresis alarm

**Authority required (STREAMLINED)**

Primary nocturnal enuresis in patients aged 6 years or older for whom an enuresis alarm is contraindicated. The reason that an alarm is contraindicated must be documented in the patient’s medical records when treatment is initiated

**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. Only one application per six months with no more than twice the maximum quantity will be authorised for the tablets.

---

**DESMOPRESSIN**

**Authority required (STREAMLINED)**

Primary nocturnal enuresis in patients aged 6 years or older who are refractory to an enuresis alarm

**Authority required (STREAMLINED)**

Primary nocturnal enuresis in patients aged 6 years or older for whom an enuresis alarm is contraindicated. The reason that an alarm is contraindicated must be documented in the patient’s medical records when treatment is initiated

**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. Only one application per six months will be authorised for the wafers. No more than twice the maximum quantity for the 120 micrograms wafers and no applications for increased maximum quantities for the 240 micrograms wafers will be authorised.

---

**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.
### Glucocorticoids

**BETAMETHASONE ACETATE + BETAMETHASONE SODIUM PHOSPHATE**

- **Restricted benefit**
  - For local intra-articular or peri-articular infiltration
- **Restricted benefit**
  - Keloid
- **Restricted benefit**
  - Lichen planus hypertrophic

betamethasone (as acetate) 2.71 mg/mL + betamethasone (as sodium phosphate) 2.96 mg/mL injection, 5 x 1 mL ampoules

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
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<tbody>
<tr>
<td>1</td>
<td></td>
<td>25.34</td>
<td>26.49</td>
<td></td>
<td>Celestone Chronodose [MK]</td>
</tr>
</tbody>
</table>

**BETAMETHASONE ACETATE + BETAMETHASONE SODIUM PHOSPHATE**

- **Restricted benefit**
  - Alopecia areata
- **Restricted benefit**
  - For local intra-articular or peri-articular infiltration
- **Restricted benefit**
  - Granulomata, dermal
- **Restricted benefit**
  - Keloid
- **Restricted benefit**
  - Lichen planus hypertrophic
- **Restricted benefit**
  - Lichen simplex chronicus
- **Restricted benefit**
  - Lupus erythematosus, chronic discoid
- **Restricted benefit**
  - Necrobiosis lipoidica
- **Restricted benefit**
  - Uveitis

**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.

betamethasone (as acetate) 2.71 mg/mL + betamethasone (as sodium phosphate) 2.96 mg/mL injection, 5 x 1 mL ampoules

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
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<td>25.34</td>
<td>26.49</td>
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<td>Celestone Chronodose [MK]</td>
</tr>
</tbody>
</table>

**CORTISONE**

**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.

cortisone acetate 25 mg tablet, 60

<table>
<thead>
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<th>Max Qty Packs</th>
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<tr>
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<td>Cortate [AS]</td>
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cortisone acetate 5 mg tablet, 50

<table>
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<td>1</td>
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<td>15.64</td>
<td>16.79</td>
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<td>Cortate [AS]</td>
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</tbody>
</table>
### DEXAMETHASONE

**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.

**DEXAMETHASONE Tablet 4 mg, 30**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
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</thead>
<tbody>
<tr>
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<td></td>
<td></td>
<td></td>
<td>Dexamethone [AS]</td>
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</table>

**DEXAMETHASONE Tablet 500 micrograms, 30**

<table>
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<tr>
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</tbody>
</table>

### DEXAMETHASONE SODIUM PHOSPHATE

**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.

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

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

**DEXAMETHASONE SODIUM PHOSPHATE Injection equivalent to 8 mg dexamethasone phosphate in 2 mL, 5**

<table>
<thead>
<tr>
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<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Dexamethone [AF]</td>
</tr>
</tbody>
</table>

### HYDROCORTISONE

**Note**

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

**hydrocortisone 20 mg tablet, 60**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Hysone 20 [AF]</td>
</tr>
</tbody>
</table>

**hydrocortisone 4 mg tablet, 50**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
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<td>Hysone 4 [AF]</td>
</tr>
</tbody>
</table>

### HYDROCORTISONE SODIUM SUCCINATE

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

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

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

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

### HYDROCORTISONE SODIUM SUCCINATE

**Restricted benefit**
For use in a hospital

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

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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<td>Solu-Cortef [PF]</td>
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</table>
### SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS

**General**

<table>
<thead>
<tr>
<th>Hydrocortisone (as sodium succinate) 100 mg injection [1 x 100 mg vial] (&amp;) inert substance diluent [1 x 2 mL vial], 1 pack</th>
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</thead>
<tbody>
<tr>
<td>5118J</td>
</tr>
<tr>
<td>Max Qty Packs</td>
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<td>6</td>
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<table>
<thead>
<tr>
<th>Hydrocortisone (as sodium succinate) 250 mg injection [1 x 250 mg vial] (&amp;) inert substance diluent [1 x 2 mL vial], 1 pack</th>
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<tbody>
<tr>
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<td>Max Qty Packs</td>
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<table>
<thead>
<tr>
<th>Hydrocortisone (as sodium succinate) 250 mg injection [1 x 250 mg vial] (&amp;) inert substance diluent [1 x 2 mL vial], 1 pack</th>
</tr>
</thead>
<tbody>
<tr>
<td>5119K</td>
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<tr>
<td>Max Qty Packs</td>
</tr>
<tr>
<td>6</td>
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### Methylprednisolone

**Restricted benefit**

For local intra-articular or peri-articular infiltration

<table>
<thead>
<tr>
<th>Methylprednisolone acetaate 40 mg/mL injection, 5 x 1 mL vials</th>
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</thead>
<tbody>
<tr>
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<table>
<thead>
<tr>
<th>Methylprednisolone acetaate 40 mg/mL injection, 5 x 1 mL vials</th>
</tr>
</thead>
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<tr>
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<tr>
<td>Max Qty Packs</td>
</tr>
<tr>
<td>1</td>
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<td>1</td>
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### 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.

<table>
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<tr>
<th>Methylprednisolone Powder for injection 40 mg (as sodium succinate), 5</th>
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<td>Max Qty Packs</td>
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<table>
<thead>
<tr>
<th>Methylprednisolone Powder for injection 40 mg (as sodium succinate), 5</th>
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### 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.

<table>
<thead>
<tr>
<th>Methylprednisolone 1 g injection [5 x 40 mg vials] (&amp;) inert substance diluent [5 x 1 mL vials], 1 pack</th>
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### Prednisolone

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<th>Prednisolone 1 mg tablet, 100</th>
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<td></td>
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</tbody>
</table>
prednisolone 25 mg tablet, 30
1916W Max Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer Brand Name and Manufacturer
1 4 .. 10.47 11.62 Panafcortelone [AS] Solone [IA]

prednisolone 5 mg tablet, 60
1917X Max Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer Brand Name and Manufacturer
1 4 .. 8.81 9.96 Panafcortelone [AS] Solone [IA]

▪ PREDNISOLONE SODIUM PHOSPHATE
prednisolone (as sodium phosphate) 5 mg/mL oral liquid, 30 mL
8285C Max Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer Brand Name and Manufacturer
† 1 5 .. 15.04 16.19 * PredMix [LN]
‡ 1 0.91 17.74 16.19 * Redipred [AS]

▪ PREDNISONE
prednisone 1 mg tablet, 100
1934T Max Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer Brand Name and Manufacturer
1 4 .. 9.20 10.35 * Predsone [LN]
‡ 0.91 10.11 10.35 * Panafcort [AS]

prednisone 25 mg tablet, 30
1936X Max Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer Brand Name and Manufacturer
1 4 .. 11.75 12.90 Panafcort [AS] Sone [IA]

prednisone 5 mg tablet, 60
1935W Max Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer Brand Name and Manufacturer
1 4 .. 9.52 10.67 Panafcort [AS] Sone [IA]

▪ TRIAMCINOLONE
Restricted benefit
For local intra-articular or peri-articular infiltration
Restricted benefit
Keloid
Restricted benefit
Lichen planus hypertrophic

triamcinolone acetonide 10 mg/mL injection, 5 x 1 mL ampoules
5233K Max Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer Brand Name and Manufacturer
‡ 1 .. .. 25.34 26.49 Kenacort-A10 [QA]

▪ TRIAMCINOLONE
Restricted benefit
Alopecia areata
Restricted benefit
For local intra-articular or peri-articular infiltration
Restricted benefit
Granulomata, dermal
Restricted benefit
Keloid
Restricted benefit
Lichen planus hypertrophic
Restricted benefit
Lichen simplex chronicus
Restricted benefit
Lupus erythematosus, chronic discoid
Restricted benefit
Necrobiosis lipoidica
Restricted benefit
Psoriasis

Note
Shared Care Model:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.
triamcinolone acetonide 10 mg/mL injection, 5 x 1 mL ampoules

2990J

Max Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer
1 .. .. 25.34 26.49 Kenacort-A10 [QA]

THYROID THERAPY

THYROID PREPARATIONS

Thyroid hormones

LITHYRONINE

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.

liothyronine sodium 20 microgram tablet, 100

2318B

Max Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer
1 2 .. 83.87 37.70 Tertroxin [QA]

THYROXINE

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.

thyroxine sodium 100 microgram tablet, 200

2175L

Max Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer
1 1 .. .. 24.32 25.47 * Eutroxsig [FM]

thyroxine sodium 200 microgram tablet, 200

2173J

Max Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer
1 1 .. .. 27.35 28.50 * Eutroxsig [FM]

thyroxine sodium 50 microgram tablet, 200

2174K

Max Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer
1 1 .. .. 23.71 24.86 * Eutroxsig [FM]

thyroxine sodium 75 microgram tablet, 200

9287T

Max Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer
1 1 .. .. 24.36 25.51 * Eutroxsig [FM]

ANTITHYROID PREPARATIONS

Thiouracils

PROPYLTHIOURACIL

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

### propylthiouracil 50 mg tablet, 100

<table>
<thead>
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<th>MRVSN $</th>
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### Sulfur-containing imidazole derivatives

#### CARBIMAZOLE

**Note**

Continuing Therapy Only:

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

#### carbimazole 5 mg tablet, 100

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<th>DPMO $</th>
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<td>Carbimazol ARISTO [PQ]</td>
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### PANCREATIC HORMONES

#### GLYCOGENOLYTIC HORMONES

- **Glycogenolytic hormones**

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

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMO $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
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<td>GlucaGen Hypokit [NO]</td>
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</table>

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

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
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<th>DPMO $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>GlucaGen Hypokit [NO]</td>
</tr>
</tbody>
</table>

### 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.

Note
Details of accepted toxicities including severity can be found on the Department of Human Services website at www.humanservices.gov.au.

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.
No increase in the maximum quantity or number of units may be authorised.
No increase in the maximum number of repeats may be authorised.
Special Pricing Arrangements apply.

teriparatide 20 microgram/dose injection, 1 x 2.4 mL cartridge

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
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<tr>
<td>1</td>
<td>5</td>
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<td>438.71</td>
<td>37.70</td>
<td>Forteo [LY]</td>
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ANTI-PARATHYROID AGENTS
Calcitonin preparations

- **SALCATION**

  Authority required (STREAMLINED)
  4938
  Symptomatic Paget disease of bone

  Authority required (STREAMLINED)
  4918
  Hypercalcaemia

Clinical criteria:
The treatment must be initiated in a hospital.

Note
The maximum quantities for calcitonin shown represent the number of individual ampoules and NOT multiples of the manufacturer’s packs. The pack size for both strengths is five ampoules.

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.

- **CINACALCET**

  Authority required (STREAMLINED)
  3673
  Maintenance therapy, following initiation and stabilisation of treatment with cinacalcet, of a patient with chronic kidney disease on dialysis who has a decrease of at least 30% in iPTH concentrations after 6 months treatment

  Authority required (STREAMLINED)
  3672
  Maintenance therapy, following initiation and stabilisation of treatment with cinacalcet, of a patient with chronic kidney disease on dialysis who has iPTH greater than 15 pmol per L and an (adjusted) serum calcium concentration of less than 2.6 mmol per L after 6 months treatment

Note
During the titration phase, intact PTH should be monitored 4 weekly (measured at least 12 hours post dose) and dose titrated until an appropriate iPTH concentration is achieved. During the titration phase, approval will be limited to sufficient supply for 4 weeks treatment at a time, with doses between 30 and 180 mg per day according to the patient’s response and tolerability.
During the maintenance phase, approval will be limited to provide sufficient quantity for 4 weeks treatment up to a maximum of 6 months supply for doses between 30 and 180 mg per day according to the patient’s response and tolerability. Intact PTH should be monitored quarterly (measured at least 12 hours post dose) and dose adjusted as necessary to maintain an appropriate iPTH concentration.

Special Pricing Arrangements apply.

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

### ANTIIINFECTIVES FOR SYSTEMIC USE

#### TETRACYCLINES

**Tetracyclines**

### DOXYCYCLINE

**Note**

Pharmaceutical benefits that have the forms doxycycline tablet 100 mg (as hydrochloride), doxycycline tablet 100 mg (as monohydrate) and doxycycline capsule: modified release 100 mg (as hydrochloride) are equivalent for the purposes of substitution.

#### doxycycline 100 mg capsule: modified release, 7 capsules

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
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<td>1</td>
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<td>8.69</td>
<td>9.00</td>
<td>* Mayne Pharma Doxycycline [YT]</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2.00</td>
<td>9.85</td>
<td>9.00</td>
<td>* Doryx [YN]</td>
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</table>

#### doxycycline 100 mg capsule: modified release, 7 capsules

<table>
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<tr>
<th>Max Qty Packs</th>
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<th>DPMQ $</th>
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<tr>
<td>1</td>
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<td>9.00</td>
<td>* Mayne Pharma Doxycycline [YT]</td>
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<tr>
<td></td>
<td></td>
<td>2.00</td>
<td>9.85</td>
<td>9.00</td>
<td>* Doryx [YN]</td>
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#### doxycycline 100 mg tablet, 7

<table>
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<td>* Doxycycline Sandoz [HX]</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>* Terry White Chemists Doxycycline [TW]</td>
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<td></td>
<td>* Terry White Chemists Doxycycline [TW]</td>
</tr>
</tbody>
</table>
### General

**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.

---

**DOXYCYCLINE**

**Restricted benefit**

**Urethritis**

**Note**
Pharmaceutical benefits that have the forms doxycycline tablet 100 mg (as hydrochloride), doxycycline tablet 100 mg (as monohydrate) and doxycycline capsule: modified release 100 mg (as hydrochloride) are equivalent for the purposes of substitution.

<table>
<thead>
<tr>
<th>doxycycline 100 mg capsule: modified release, 21 capsules</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
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<th>DPMQ $</th>
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<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tr>
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<td></td>
<td></td>
<td></td>
<td>&quot;^2 Doryx [YN]&quot;</td>
</tr>
</tbody>
</table>

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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.

<table>
<thead>
<tr>
<th>doxycycline 100 mg capsule: modified release, 7 capsules</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
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<td>&quot;^1 Mayne Pharma Doxycycline [YT]&quot;</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>8.00</td>
<td>19.12</td>
<td>12.27</td>
<td>&quot;^2 Doryx [YN]&quot;</td>
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</table>

<table>
<thead>
<tr>
<th>doxycycline 100 mg tablet, 7</th>
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<th>No. of Rpts</th>
<th>Premium $</th>
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<td>8.00</td>
<td>19.12</td>
<td>12.27</td>
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<table>
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<th>doxycycline 100 mg tablet, 7</th>
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<td></td>
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<td>8.00</td>
<td>19.12</td>
<td>12.27</td>
<td>&quot;^2 Doryx [YN]&quot;</td>
</tr>
</tbody>
</table>

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**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.
**ANTIINFECTIVES FOR SYSTEMIC USE**

**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.

<p>| doxycycline 50 mg capsule: modified release, 25 capsules |</p>
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<thead>
<tr>
<th>MaxQty</th>
<th>No. of Rpts</th>
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<p>| doxycycline 50 mg tablet, 25 |</p>
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<td>5</td>
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<td>12.57</td>
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<p>| doxycycline 50 mg tablet, 25 |</p>
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<tr>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>* Frakas [QA]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Terry White Chemists Doxycycline [TW]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Doxycycline Sandoz [HX]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* GenRx Doxycycline [GX]</td>
</tr>
</tbody>
</table>

**MINOCYCLINE**

**Caution**
There are concerns about the incidence of benign intracranial hypertension associated with this drug.

**Restricted benefit**
Severe acne not responding to other tetracyclines

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

<p>| minocycline 50 mg tablet, 60 |</p>
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<th>No. of Rpts</th>
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<td>16.54</td>
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<td></td>
<td>1.89</td>
<td>17.28</td>
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**BETA-LACTAM ANTIBACTERIALS, PENICILLINS**

**Penicillins with extended spectrum**

**AMOXYCILLIN**

<p>| amoxycillin 100 mg/mL oral liquid: powder for, 20 mL |</p>
<table>
<thead>
<tr>
<th>MaxQty</th>
<th>No. of Rpts</th>
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<th>DPMQ $</th>
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<th>Brand Name and Manufacturer</th>
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</table>

<p>| amoxycillin 100 mg/mL oral liquid: powder for, 20 mL |</p>
<table>
<thead>
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<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
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<p>| amoxycillin 125 mg/5 mL oral liquid: powder for, 100 mL |</p>
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<th>No. of Rpts</th>
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</tr>
<tr>
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<td></td>
<td></td>
<td></td>
<td>* APO-Amoxycillin [TX]</td>
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<td></td>
<td>* Chem mart Amoxycillin [CH]</td>
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<td></td>
<td></td>
<td></td>
<td>* Ranmox [RA]</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>#2.89</td>
<td>#12.96</td>
<td>* Amoxycillin Sandoz [SZ]</td>
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<td></td>
<td></td>
<td></td>
<td>* Bgramin [GN]</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>* GenRx Amoxycillin [GX]</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>* Terry White Chemists Amoxycillin [TW]</td>
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<p>| amoxycillin 125 mg/5 mL oral liquid: powder for, 100 mL |</p>
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<th>No. of Rpts</th>
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<td>* Chem mart Amoxycillin [CH]</td>
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<td>* Ranmox [RA]</td>
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<td>* Bgramin [GN]</td>
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<td>Cilamox [QA]</td>
<td>Chem mart Amoxicillin [CH]</td>
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<tr>
<td>Yomax 500 [DO]</td>
<td>Terry White Chemists Amoxicillin [TW]</td>
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<td>Amoxicillin 500 mg capsule, 20</td>
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<th>Brand Name and Manufacturer</th>
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<tbody>
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<td>Maxamox [SZ]</td>
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<td>5.21</td>
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</table>
### AMOXICILLIN

**Restricted benefit**
Acute exacerbations of chronic bronchitis

### AMOXICILLIN

**Authority required**
Treatment of infections suspected or proven to be due to a susceptible organism in patients who require a liquid formulation and in whom the syrup formulations are unsuitable

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>AMOXICILLIN</th>
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</thead>
<tbody>
<tr>
<td>Amoxil [AS]</td>
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### AMPICILLIN

ampicillin 1 g injection, 5 x 1 g vials

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>AMPICILLIN</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ampicyn [AF]</td>
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</table>

### BENZATHINE BENZYLPCINICILLIN

BENZATHINE BENZYLPCINICILLIN Injection 900 mg in 2.3 mL single use pre-filled syringe, 10

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>BENZATHINE BENZYLPCINICILLIN</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bicillin L-A [PF]</td>
<td></td>
</tr>
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</table>

### BENZYLPCINICILLIN

benzylpenicillin 3 g injection, 1 x 3 g vial

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>BENZYLPCINICILLIN</th>
</tr>
</thead>
<tbody>
<tr>
<td>BenPen [CS]</td>
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</table>

benzylpenicillin 600 mg injection, 1 x 600 mg vial

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>BENZYLPCINICILLIN</th>
</tr>
</thead>
<tbody>
<tr>
<td>BenPen [CS]</td>
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### Antiinfectives for Systemic Use

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Schedule of Pharmaceutical Benefits</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Benylpenicillin 600 mg injection, 1 x 600 mg vial</strong></td>
<td>3398W</td>
</tr>
<tr>
<td>Max Qty Packs</td>
<td>No. of Rpts</td>
</tr>
<tr>
<td>10</td>
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**Phenoxymethylpenicillin**

<table>
<thead>
<tr>
<th>Product Description</th>
<th>Schedule of Pharmaceutical Benefits</th>
</tr>
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<tbody>
<tr>
<td>Phenoxymethylpenicillin 125 mg/5 mL oral liquid: powder for, 100 mL</td>
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<tr>
<td>Max Qty Packs</td>
<td>No. of Rpts</td>
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<tr>
<td>2</td>
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<table>
<thead>
<tr>
<th>Product Description</th>
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<tr>
<td>Phenoxymethylpenicillin 150 mg/5 mL oral liquid, 100 mL</td>
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<tr>
<td>Max Qty Packs</td>
<td>No. of Rpts</td>
</tr>
<tr>
<td>2</td>
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<table>
<thead>
<tr>
<th>Product Description</th>
<th>Schedule of Pharmaceutical Benefits</th>
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<tr>
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<table>
<thead>
<tr>
<th>Product Description</th>
<th>Schedule of Pharmaceutical Benefits</th>
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</thead>
<tbody>
<tr>
<td>Phenoxymethylpenicillin 250 mg capsule, 50</td>
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<tr>
<td>Max Qty Packs</td>
<td>No. of Rpts</td>
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<tr>
<th>Product Description</th>
<th>Schedule of Pharmaceutical Benefits</th>
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<tbody>
<tr>
<td>Phenoxymethylpenicillin 250 mg capsule, 50</td>
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<td>No. of Rpts</td>
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<table>
<thead>
<tr>
<th>Product Description</th>
<th>Schedule of Pharmaceutical Benefits</th>
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</thead>
<tbody>
<tr>
<td>Phenoxymethylpenicillin 250 mg tablet, 25</td>
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<tr>
<td>Max Qty Packs</td>
<td>No. of Rpts</td>
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<thead>
<tr>
<th>Product Description</th>
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<td>Phenoxymethylpenicillin 250 mg tablet, 25</td>
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<th>Product Description</th>
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</thead>
<tbody>
<tr>
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<th>Product Description</th>
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</thead>
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</table>
### Antiinfectives for Systemic Use

#### Phenoxymethylpenicillin

**500 mg tablet, 25**

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<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium ($)</th>
<th>DPMQ ($)</th>
<th>MRVSN ($)</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>..</td>
<td>*14.00</td>
<td>15.15</td>
<td></td>
<td>Abbocillin-VK Filmtab [QA]</td>
</tr>
</tbody>
</table>

**Restricted benefit**

Prophylaxis of recurrent streptococcal infections (including rheumatic fever)

#### Procaine Penicillin

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

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium ($)</th>
<th>DPMQ ($)</th>
<th>MRVSN ($)</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>..</td>
<td>92.56</td>
<td>37.70</td>
<td></td>
<td>Cilicaine [QA]</td>
</tr>
</tbody>
</table>

#### Dicloxacillin

**Beta-lactamase resistant penicillins**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
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<th>DPMQ ($)</th>
<th>MRVSN ($)</th>
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<td>..</td>
<td>92.56</td>
<td>37.70</td>
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<td>Cilicaine [QA]</td>
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</table>

### Flucloxacillin

<table>
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<tr>
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<tbody>
<tr>
<td>1</td>
<td>..</td>
<td>17.85</td>
<td>19.00</td>
<td></td>
<td>Distaph 500 [AF]</td>
</tr>
</tbody>
</table>

**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.

**1 g injection, 5 x 1 g vials**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
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<th>DPMQ ($)</th>
<th>MRVSN ($)</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>..</td>
<td>*11.91</td>
<td>13.06</td>
<td></td>
<td>* Flubiclox [GN]</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
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<th>DPMQ ($)</th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>..</td>
<td>17.85</td>
<td>19.00</td>
<td></td>
<td>* Flucil [AS]</td>
</tr>
</tbody>
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<table>
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<tbody>
<tr>
<td>1</td>
<td>..</td>
<td>10.05</td>
<td>11.20</td>
<td></td>
<td>* Flucil [AS]</td>
</tr>
</tbody>
</table>
### FLUCLOXACILLIN

**Caution**
Severe cholestatic hepatitis has been reported with this drug. Significant risk factors are age, particularly greater than 55 years, and duration of treatment longer than 14 days.

**Restricted benefit**
Serious staphylococcal infections

#### Flucloxacillin 125 mg/5 mL oral liquid: powder for, 100 mL

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>§1</td>
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<td>..</td>
<td>#16.44</td>
<td>17.94</td>
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#### Flucloxacillin 250 mg capsule, 24

<table>
<thead>
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<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>§1</td>
<td>..</td>
<td>..</td>
<td>#19.97</td>
<td>21.47</td>
<td>Staphylex 250 [AF]</td>
</tr>
</tbody>
</table>

#### Flucloxacillin 500 mg capsule, 24

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>§1</td>
<td>..</td>
<td>..</td>
<td>#19.97</td>
<td>21.47</td>
<td>Staphylex 500 [AF]</td>
</tr>
</tbody>
</table>

#### AMOXYCILLIN + CLAVULANIC ACID

**Caution**
Hepatotoxicity has been reported with this drug.

**Restricted benefit**
Infections where resistance to amoxycillin is suspected

**Restricted benefit**
Infections where resistance to amoxycillin is proven

#### Amoxycillin 125 mg/5 mL + clavulanic acid 31.25 mg/5 mL oral liquid: powder for, 75 mL

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>§2</td>
<td>1</td>
<td>.</td>
<td>10.76</td>
<td>12.26</td>
<td>APO-Amoxycillin and Clavulanic Acid 125/31.25 [TX]</td>
</tr>
<tr>
<td>2.89</td>
<td>13.65</td>
<td>12.26</td>
<td>Augmentin [AS]</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### Amoxycillin 125 mg/5 mL + clavulanic acid 31.25 mg/5 mL oral liquid: powder for, 75 mL

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
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<tbody>
<tr>
<td>§2</td>
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<td>10.76</td>
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</tr>
<tr>
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<td>13.65</td>
<td>12.26</td>
<td>Augmentin [AS]</td>
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</table>
### Antiinfectives for Systemic Use

**Amoxicillin 400 mg/5 mL + Clavulanic Acid 57 mg/5 mL Oral Liquid: Powder for, 60 mL**

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
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</thead>
<tbody>
<tr>
<td>APO-Amoxicillin and Clavulanic Acid 400/57 [TX]</td>
<td>#11.36</td>
<td>12.86</td>
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<tr>
<td>Clamoxyl Duo 400 [AL]</td>
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<tr>
<td>GA-Amclav Forte 400/57 [GN]</td>
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**Amoxicillin 400 mg/5 mL + Clavulanic Acid 57 mg/5 mL Oral Liquid: Powder for, 60 mL**

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<tr>
<td>GA-Amclav Forte 400/57 [GN]</td>
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</table>

**Amoxicillin 500 mg + Clavulanic Acid 125 mg Tablet, 10**

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
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<tbody>
<tr>
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<td>Clamoxyl Duo [AL]</td>
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<td>GA-Amclav 500/125 [GN]</td>
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<tr>
<td>Pharmacor AmoxyClav 500/125 [CR]</td>
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**Amoxicillin 500 mg + Clavulanic Acid 125 mg Tablet, 10**

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<td>Pharmacor AmoxyClav 500/125 [CR]</td>
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**Amoxicillin 875 mg + Clavulanic Acid 125 mg Tablet, 10**

<table>
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<tr>
<th>Brand Name and Manufacturer</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
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<tr>
<td>Amoxyclav AN 875/125 [EA]</td>
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<tr>
<td>AmoxyClav RBX 875/125 [RA]</td>
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<td>Chem mart Amoxyclav and Clavulanic Acid [CH]</td>
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<tr>
<td>Clamoxyl Duo forte [AL]</td>
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</tr>
<tr>
<td>Curam Duo 500/125 [SZ]</td>
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<tr>
<td>GA-Amclav Forte 875/125 [GN]</td>
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</tr>
<tr>
<td>Pharmacor AmoxyClav 875/125 [CR]</td>
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**Amoxicillin 875 mg + Clavulanic Acid 125 mg Tablet, 10**

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**Amoxicillin 875 mg + Clavulanic Acid 125 mg Tablet, 10**

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**Amoxicillin 875 mg + Clavulanic Acid 125 mg Tablet, 10**

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**Amoxicillin 875 mg + Clavulanic Acid 125 mg Tablet, 10**

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**Ticarcillin + Clavulanic Acid**

*Restricted benefit*

Infections where positive bacteriological evidence confirms that this antibiotic is an appropriate therapeutic agent.
### TICARÇILLİN + 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.

---

### OTHER Beta-LACTAM ANTIBACTERIALS

**First-generation cephalosporins**

#### CEPHALEXIN

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### CEPHALEXIN 125 mg/5 mL oral liquid: powder for, 100 mL

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### CEPHALEXIN

**Authority required (STREAMLINED)**

**4243**

Prophylaxis of urinary tract infection

### cephalaxin 250 mg/5 mL oral liquid: powder for, 100 mL

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- **6.23** | **17.62** | 12.89 | * Keflex [AS]

### cephalaxin 250 mg/5 mL oral liquid: powder for, 100 mL

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### cephalaxin 500 mg capsule, 20

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- **6.31** | **15.09** | 9.93 | * Keflex [AS]

### cephalaxin 500 mg capsule, 20

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### CEPHALOTHIN

### cephalothin 1 g injection, 10 x 1 g vials

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### cephalothin 1 g injection, 10 x 1 g vials

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**CEPHAZOLIN**

**Restricted benefit**

**Cellulitis**

**cephazolin 2 g injection, 1 x 2 g vial**

<table>
<thead>
<tr>
<th>5479J</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>10</td>
<td>..</td>
<td>..</td>
<td>*23.76</td>
<td>24.91</td>
<td></td>
<td>Cefazolin Sandoz [SZ]</td>
</tr>
</tbody>
</table>

* Cephazolin Alphapharm [AF]

**cephazolin 500 mg injection, 5 x 500 mg vials**

<table>
<thead>
<tr>
<th>5477G</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>..</td>
<td>..</td>
<td>*12.38</td>
<td>13.53</td>
<td></td>
<td>Cefazolin-AFT [AE]</td>
</tr>
</tbody>
</table>

**CEPHAZOLIN**

**Restricted benefit**

**Cellulitis**

**Note**

For item codes 5478H and 1799Q, pharmaceutical benefits that have the form powder for injection 1 g are equivalent for the purposes of substitution.

**cephazolin 1 g injection, 10 x 1 g vials**

<table>
<thead>
<tr>
<th>5478H</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>..</td>
<td>..</td>
<td>14.20</td>
<td>15.35</td>
<td></td>
<td>Cefazolin Sandoz [SZ]</td>
</tr>
</tbody>
</table>

**cephazolin 1 g injection, 5 x 1 g vials**

<table>
<thead>
<tr>
<th>1799Q</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>2</td>
<td>..</td>
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<td>*14.22</td>
<td>15.37</td>
<td></td>
<td>Cefazolin-AFT [AE]</td>
</tr>
</tbody>
</table>

* Hospira Cefazolin Sodium [HH]

**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 arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**cephazolin 2 g injection, 1 x 2 g vial**

<table>
<thead>
<tr>
<th>9326W</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>10</td>
<td>..</td>
<td>..</td>
<td>*23.76</td>
<td>24.91</td>
<td></td>
<td>Cefazolin Sandoz [SZ]</td>
</tr>
</tbody>
</table>

* Cephazolin Alphapharm [AF]

**cephazolin 500 mg injection, 5 x 500 mg vials**

<table>
<thead>
<tr>
<th>1256D</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>..</td>
<td>..</td>
<td>*12.38</td>
<td>13.53</td>
<td></td>
<td>Cefazolin-AFT [AE]</td>
</tr>
</tbody>
</table>

**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**

For item codes 1257E and 1797N, pharmaceutical benefits that have the form powder for injection 1 g are equivalent for the purposes of substitution.

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.
### CEFACLOR

#### Caution

Serum sickness-like reactions have been reported with this drug, especially in children.

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>DPMO</th>
<th>MRVSN</th>
<th>Premium</th>
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</thead>
<tbody>
<tr>
<td>Aclor 125 [QA]</td>
<td>#12.07</td>
<td>13.57</td>
<td>14.20</td>
</tr>
<tr>
<td>GenRx Cefaclor [GX]</td>
<td>#12.07</td>
<td>13.57</td>
<td>15.35</td>
</tr>
<tr>
<td>Keflor [AF]</td>
<td>#12.07</td>
<td>13.57</td>
<td>14.20</td>
</tr>
<tr>
<td>Aclor 250 [QA]</td>
<td>#12.07</td>
<td>13.57</td>
<td>14.20</td>
</tr>
<tr>
<td>GenRx Cefaclor [GX]</td>
<td>#12.07</td>
<td>13.57</td>
<td>15.35</td>
</tr>
<tr>
<td>Keflor [AF]</td>
<td>#12.07</td>
<td>13.57</td>
<td>14.20</td>
</tr>
<tr>
<td>Aclor 375 [QA]</td>
<td>#12.07</td>
<td>13.57</td>
<td>14.20</td>
</tr>
<tr>
<td>GenRx Cefaclor [GX]</td>
<td>#12.07</td>
<td>13.57</td>
<td>15.35</td>
</tr>
<tr>
<td>Keflor [AF]</td>
<td>#12.07</td>
<td>13.57</td>
<td>14.20</td>
</tr>
</tbody>
</table>

### CEFUROXIME AXETIL

#### Powder for oral suspension 125 mg (base) per 5 mL, 70 mL, 1

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>DPMO</th>
<th>MRVSN</th>
<th>Premium</th>
</tr>
</thead>
<tbody>
<tr>
<td>Zinnat [AS]</td>
<td>#19.80</td>
<td>21.30</td>
<td>17.79</td>
</tr>
<tr>
<td>Zinnat [AS]</td>
<td>#19.80</td>
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<td>17.79</td>
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<tr>
<td>Zinnat [AS]</td>
<td>#19.80</td>
<td>21.30</td>
<td>17.79</td>
</tr>
<tr>
<td>Zinnat [AS]</td>
<td>#19.80</td>
<td>21.30</td>
<td>17.79</td>
</tr>
<tr>
<td>Zinnat [AS]</td>
<td>#19.80</td>
<td>21.30</td>
<td>17.79</td>
</tr>
</tbody>
</table>

### CEFUROXIME AXETIL Powder for oral suspension 125 mg (base) per 5 mL, 70 mL, 1

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>DPMO</th>
<th>MRVSN</th>
<th>Premium</th>
</tr>
</thead>
<tbody>
<tr>
<td>Zinnat [AS]</td>
<td>#19.80</td>
<td>21.30</td>
<td>17.79</td>
</tr>
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<td>Zinnat [AS]</td>
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<td>21.30</td>
<td>17.79</td>
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<tr>
<td>Zinnat [AS]</td>
<td>#19.80</td>
<td>21.30</td>
<td>17.79</td>
</tr>
<tr>
<td>Zinnat [AS]</td>
<td>#19.80</td>
<td>21.30</td>
<td>17.79</td>
</tr>
</tbody>
</table>
**Third-generation cephalosporins**

- **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.

  **CEFOTAXIME Powder for injection 1 g, 10**

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMO $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>..</td>
<td>21.47</td>
<td>22.62</td>
<td>* Hospira Pty Limited [HH]</td>
<td></td>
</tr>
</tbody>
</table>

- **CEFOTAXIME**
  - **Restricted benefit**
  
  Infections where positive bacteriological evidence confirms that this antibiotic is an appropriate therapeutic agent

  **Note**
  
  For item codes 5049R and 1769D, pharmaceutical benefits that have the form powder for injection 2 g are equivalent for the purposes of substitution.

  **CEFOTAXIME Powder for injection 2 g, 10**

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMO $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
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<td>33.96</td>
<td>35.11</td>
<td>* Hospira Pty Limited [HH]</td>
<td></td>
</tr>
</tbody>
</table>

- **CEFOTAXIME**
  - **Restricted benefit**
  
  Infections where positive bacteriological evidence confirms that this antibiotic is an appropriate therapeutic agent

  **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.

  **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.

  **CEFOTAXIME Powder for injection 1 g, 10**

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMO $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>..</td>
<td>21.47</td>
<td>22.62</td>
<td>* Hospira Pty Limited [HH]</td>
<td></td>
</tr>
</tbody>
</table>

- **CEFOTAXIME**
  - **Restricted benefit**
  
  Infections where positive bacteriological evidence confirms that this antibiotic is an appropriate therapeutic agent

  **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.

  **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.
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.

**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.

**CEFOTAXIME Powder for injection 2 g, 10**

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
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<tbody>
<tr>
<td>1759N</td>
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<td>33.96</td>
<td>* Hospira Pty Limited [HH]</td>
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</table>

**cefotaxime 2 g injection, 1 x 2 g vial**

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>1086E</td>
<td>10</td>
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<td>..</td>
<td>34.06</td>
<td>* Cefotaxime Sandoz [SZ]</td>
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</table>

**CEFTRIAXONE**

**Restricted benefit**

Gonorrhoea

**ceftriaxone 500 mg injection, 1 x 500 mg vial**

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tr>
<td>9058R</td>
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<td>7.63</td>
<td>* Ceftriaxone-AFT [AE]</td>
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</table>

**CEFTRIAXONE**

**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 1784X and 1788D, pharmaceutical benefits that have the form powder for injection 1 g are equivalent for the purposes of substitution.

**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.

**ceftriaxone 2 g injection, 1 x 2 g vial**

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>1785Y</td>
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<td>..</td>
<td>..</td>
<td>19.56</td>
<td>* Ceftriaxone-AFT [AE]</td>
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**ceftriaxone 500 mg injection, 1 x 500 mg vial**

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
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<tbody>
<tr>
<td>1783W</td>
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</table>

**CEFTRIAXONE**

**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 1784X and 1788D, pharmaceutical benefits that have the form powder for injection 1 g are equivalent for the purposes of substitution.

**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**

**CEFTRIAXONE Powder for injection 1 g, 5**

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>..</td>
<td>13.68</td>
<td>14.83</td>
<td>..</td>
<td>* Ceftriaxone Alphapharm [AF] * Max Pharma Ceftriaxone [GQ]</td>
<td></td>
</tr>
</tbody>
</table>

**ceftriaxone 1 g injection, 1 x 1 g vial**

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
</table>

**Fourth-generation cephalosporins**

- **CEFEPIME**
  - Authority required
  - Treatment of febrile neutropenia

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

| CEFEPIME Powder for injection 1 g (as hydrochloride), 1 |
|-------------|------------------|------------------|------------------|------------------|------------------|
| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
| 10           | ..          | *60.66     | 37.70   | ..      | * Cefepime-AFT [AE] * Cefepime Sandoz [SZ] * DBL Cefepime [HH] |

| CEFEPIME Powder for injection 2 g (as hydrochloride), 1 |
|-------------|------------------|------------------|------------------|------------------|------------------|
| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
| 10           | ..          | *109.36     | 37.70   | ..      | * Cefepime-AFT [AE] * Cefepime Sandoz [SZ] * DBL Cefepime [HH] |

**SULFONAMIDES AND TRIMETHOPRIM**

- **TRIMETHOPRIM**

  **Trimethoprim and derivatives**

| trimethoprim 300 mg tablet, 7 |
|-------------------------------|------------------|------------------|------------------|------------------|
| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
| 1              | 1             | 8.72       | 9.87   | ..      | * Alprim [AF] * Triprim [QA] |

- **TRIMETHOPRIM**

  **Authority required (STREAMLINED) 4243**

  Prophylaxis of urinary tract infection

| trimethoprim 300 mg tablet, 7 |
|-------------------------------|------------------|------------------|------------------|------------------|
| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
| 2              | 2             | *10.68      | 11.83  | ..      | * Alprim [AF] * Triprim [QA] |

**Combinations of sulfonamides and trimethoprim, incl. derivatives**

- **TRIMETHOPRIM + SULFAMETHOXAZOLE**

  **Caution**
  - There is an increased risk of severe adverse reactions with this combination in the elderly.

| trimethoprim 160 mg + sulfamethoxazole 800 mg tablet, 10 |
|--------------------------------------------------------|------------------|------------------|------------------|------------------|
| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
| 1              | 1             | 9.58       | 10.73  | ..      | * Bactrim DS [RO] * Resprim Forte [AF] |

| trimethoprim 160 mg + sulfamethoxazole 800 mg tablet, 10 |
|--------------------------------------------------------|------------------|------------------|------------------|------------------|
| Max.Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer | Brand Name and Manufacturer |
| 1              | ..          | 9.58       | 10.73  | ..      | * Bactrim DS [RO] * Resprim Forte [AF] |

**Schedule of Pharmaceutical Benefits** 203
### General

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium ($)</th>
<th>DPMQ ($)</th>
<th>MRVSN ($)</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<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></td>
<td></td>
<td></td>
<td>4.25</td>
<td></td>
<td>Seprin [QA]</td>
</tr>
</tbody>
</table>

### MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS

#### Macrolides

- **AZITHROMYCIN**
  - Restricted benefit
  - Trachoma

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

- **AZITHROMYCIN**
  - Restricted benefit
  - Uncomplicated urethritis due to Chlamydia trachomatis
  - Uncomplicated cervicitis due to Chlamydia trachomatis

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

### CLARITHROMYCIN

- **clarithromycin 250 mg tablet, 14**

  **Note**
  - Restricted benefit
  - Bordetella pertussis
  - Atypical mycobacterial infections
<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Max Qty Packs</th>
<th>No.of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
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<td></td>
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<tr>
<td>clarithromycin 250 mg/5 mL oral liquid: powder for, 50 mL</td>
<td></td>
<td></td>
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<tr>
<td>Klacid [GO]</td>
<td>9192T</td>
<td>1</td>
<td>..</td>
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<td>#27.92 29.42</td>
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<tr>
<td>erythromycin 250 mg capsule: enteric, 25</td>
<td>1404X</td>
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<td>11.03 12.18</td>
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<tr>
<td>Eryc [YN]</td>
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<td>..</td>
<td>..</td>
<td>#2.91 13.94 12.18</td>
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<tr>
<td>erythromycin 250 mg capsule: enteric, 25</td>
<td>3325B</td>
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<tr>
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<td>*196.81 37.70</td>
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<tr>
<td>Erythrocin-I.V. [LM]</td>
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### Roxithromycin 150 mg tablet, 10

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### Roxithromycin 300 mg tablet, 5

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### Roxithromycin 300 mg tablet, 5

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### Roxithromycin 50 mg tablet: dispersible, 10

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<td>Rulide D [SW]</td>
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### Roxithromycin 50 mg tablet: dispersible, 10

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<tr>
<td>1</td>
<td>1</td>
<td>13.23</td>
<td>14.38</td>
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<td>Rulide D [SW]</td>
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### Clindamycin

**Restricted benefit**

Gram-positive coccal infections where these cannot be safely and effectively treated with a penicillin

### Clindamycin 150 mg capsule, 24

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<td>Clindamycin [CH]</td>
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<td></td>
<td>Cleocin [FZ]</td>
<td>Clindamycin-Link [LM]</td>
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<td></td>
<td></td>
<td>Terry White Chemists</td>
<td>Clindamycin-Link [LM]</td>
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<td>Clindamycin [TX]</td>
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### Clindamycin 150 mg capsule, 24

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<tr>
<td>1</td>
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<td>Dalacin C [PF]</td>
<td>Clindamycin [TX]</td>
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<td>Cleocin [FZ]</td>
<td>Clindamycin-Link [LM]</td>
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<td>Terry White Chemists</td>
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### Lincosamides

- **Clindamycin**

  **Restricted benefit**

  Gram-positive coccal infections where these cannot be safely and effectively treated with a penicillin
## Antiinfectives for Systemic Use

### Lincomycin

Lincomycin 600 mg/2 mL injection, 5 x 2 mL vials

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<tr>
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<th>No. of Rpts</th>
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<tbody>
<tr>
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<td>Lincocin [PF]</td>
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Lincomycin 600 mg/2 mL injection, 5 x 2 mL vials

<table>
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</table>

### Amino glycoside Antibacterials

#### Gentamicin

Gentamicin 80 mg/2 mL injection, 10 x 2 mL ampoules

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<tbody>
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<td>21.16</td>
<td>Pfizer Australia Pty Ltd [PF]</td>
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#### Tobramycin

Tobramycin 500 mg/5 mL injection, 10 x 5 mL vials

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### Tobramycin

Tobramycin 300 mg/5 mL inhalation: solution, 56 x 5 mL ampoules

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### Tobramycin

Tobramycin 80 mg/2 mL injection, 5 x 2 mL vials

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<td>37.70</td>
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Tobramycin Injection 80 mg (base) in 2 mL (without preservative), 5

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### Tobramycin

Tobramycin 80 mg/2 mL injection, 5 x 2 mL vials

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Tobramycin Injection 80 mg (base) in 2 mL (without preservative), 5

<table>
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<tr>
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<tbody>
<tr>
<td>8872Y</td>
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<td>*65.36</td>
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<td>37.70</td>
<td>Pfizer Australia Pty Ltd [PF]</td>
</tr>
</tbody>
</table>

### Authority required (STREAMLINED)

4456

Proven Pseudomonas aeruginosa infection

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must have cystic fibrosis, AND
- Patient must have been assessed for bronchial hyperresponsiveness as per the TGA-approved Product Information, with a negative test result, AND
Patient must be participating in a four week trial of tobramycin inhalation powder and will be assessed for ability to tolerate the dry powder formulation in order to qualify for continued PBS-subsidised therapy. The trial commencement date must be documented in the patient’s medical records.

**Population criteria:**
Patient must be 6 years of age or older.

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

tobramycin 28 mg inhalation, 224 capsules

<table>
<thead>
<tr>
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<td>10066T</td>
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<td>2549.70</td>
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<td>TOBI podhaler [NV]</td>
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### 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, **and** 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.
No increase in the maximum number of repeats may be authorised.
Special Pricing Arrangements apply.

tobramycin 28 mg inhalation, 224 capsules

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
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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

ciprofloxacin 500 mg tablet, 14

<table>
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<td>18.57</td>
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<td></td>
<td>* Cifran [RA]</td>
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<td></td>
<td>* Ciprofloxacin 500 [CR]</td>
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<td>* Ciprofloxacin-BW [GQ]</td>
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<td>* Ciprofloxacin-GA [GN]</td>
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<td>* Ciprol 500 [QA]</td>
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<td>* Loxip 500 [DO]</td>
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Note: 1.40 18.82 18.57  * Ciproxin 500 [BN]

**Ciprofloxacin 750 mg tablet, 14**

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<td>* Ciprofloxacin-BW [GQ]</td>
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<td></td>
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<td></td>
<td>* Ciprofloxacin Sandoz [SZ]</td>
</tr>
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<td></td>
<td></td>
<td>* GenRx Ciprofloxacin [GX]</td>
</tr>
<tr>
<td></td>
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<td></td>
<td></td>
<td></td>
<td>* Ciprofloxacin-DRLA [RZ]</td>
</tr>
</tbody>
</table>

Note: 1.40 18.82 18.57  * Ciproxin 750 [BN]
**ANTIINFECTIVES FOR SYSTEMIC USE**

---

### CIPROFLOXACIN

**Authority required**

- Respiratory tract infection proven or suspected to be caused by *Pseudomonas aeruginosa* in severely immunocompromised patients
- Bacterial gastroenteritis in severely immunocompromised patients
- Treatment of infections proven to be due to *Pseudomonas aeruginosa* or other gram-negative bacteria resistant to all other oral antimicrobials
- 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

**Ciprofloxacin 250 mg tablet, 14**

<table>
<thead>
<tr>
<th>Max.Qty</th>
<th>Packs</th>
<th>No. of Rpts</th>
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<th>DPMO $</th>
<th>MRVSN $</th>
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<tbody>
<tr>
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<td><strong>C-Flox 250 [AL]</strong></td>
<td><strong>Ciprofloxacin [GA]</strong></td>
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<td></td>
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<td>12.21</td>
<td>13.36</td>
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<td><strong>Ciprofloxacin Sandoz [SZ]</strong></td>
<td><strong>Ciprol 750 [DO]</strong></td>
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<td><strong>GenRx Ciprofloxacin [GX]</strong></td>
<td><strong>Ciprofloxacin [GA]</strong></td>
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**NORFLOXACIN**

**Authority required**

- Acute bacterial enterocolitis
- Complicated urinary tract infection

**Norfloxacin 400 mg tablet, 14**

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<td><strong>Nufloxib [AF]</strong></td>
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<td><strong>Norfloxacin-DRLA [RZ]</strong></td>
<td><strong>Roxin [QA]</strong></td>
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</tbody>
</table>

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### OTHER ANTIBACTERIALS

#### Glycopeptide antibacterials

**VANCOMYCIN**

- **Restricted benefit**
- Prophylaxis of endocarditis in patients hypersensitive to penicillin

**Vancocin 1 g injection, 1 x 1 g vial**

<table>
<thead>
<tr>
<th>Max.Qty</th>
<th>Packs</th>
<th>No. of Rpts</th>
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<th>DPMO $</th>
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<td><strong>Vancocin CP [AS]</strong></td>
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<td><strong>Vancomycin Sandoz [SZ]</strong></td>
<td><strong>Vancocin Alphapharm [AF]</strong></td>
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<td></td>
<td><strong>Vycin IV [GN]</strong></td>
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**Vancocin 1 g injection, 1 x 1 g vial**

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**Vancocin 500 mg injection, 1 x 500 mg vial**

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<td></td>
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<td><strong>Vancocin Sandoz [SZ]</strong></td>
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<td></td>
<td><strong>Vancocin Alphapharm [AF]</strong></td>
<td><strong>Vancocin Sandoz [SZ]</strong></td>
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**Vancocin 500 mg injection, 1 x 500 mg vial**

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<td><strong>Vancomycin Alphapharm [AF]</strong></td>
<td><strong>Vancocin Sandoz [SZ]</strong></td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td><strong>Vancocin Alphapharm [AF]</strong></td>
<td><strong>Vancocin Sandoz [SZ]</strong></td>
</tr>
</tbody>
</table>

---

**VANCOMYCIN**

- **Restricted benefit**
- Endophthalmitis
- **Restricted benefit**
Use initiated in a hospital for infections where vancomycin is an appropriate antibiotic

<table>
<thead>
<tr>
<th>vancomycin 1 g injection, 1 x 1 g vial</th>
<th>Brand Name and Manufacturer</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>2270L</td>
<td>* Hospira Pty Limited [HH]</td>
<td>* Vancomycin Sandoz [SZ]</td>
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<tr>
<td></td>
<td>* Vancomycin Alphapharm [AF]</td>
<td>* Vycin IV [GN]</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>vancomycin 500 mg injection, 1 x 500 mg vial</th>
<th>Brand Name and Manufacturer</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>3131T</td>
<td>* Hospira Pty Limited [HH]</td>
<td>* Vancomycin CP [AS]</td>
</tr>
<tr>
<td></td>
<td>* Vancomycin Alphapharm [AF]</td>
<td>* Vancomycin Sandoz [SZ]</td>
</tr>
</tbody>
</table>

**Steroid antibacterials**

- **FUSIDATE**
  - Restricted benefit
  - Serious staphylococcal infections
  - Clinical criteria:
    - The treatment must be used in combination with another antibiotic, **AND**
    - The condition must be proven to be due to a staphylococcus.

<table>
<thead>
<tr>
<th>fusidate sodium 250 mg tablet, 36</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>2312Q</td>
<td>Fucidin [CS]</td>
</tr>
</tbody>
</table>

**Imidazole derivatives**

- **METRONIDAZOLE**
  - metronidazole 200 mg tablet, 21
    - 1636D
      - 1 1 .. 8.22 9.37 * Metrogyl 200 [AF] * Metronide 200 [AV]
      - 2.30 10.52 9.37 * Flagyl [SW]
  - metronidazole 200 mg tablet, 21
    - 3339R
      - 2.30 10.52 9.37 * Flagyl [SW]
  - metronidazole 200 mg/5 mL oral liquid, 100 mL
    - 1630T
      - .. .. .. 19.16 20.31 Flagyl S [SW]
  - metronidazole 200 mg/5 mL oral liquid, 100 mL
    - 3341W
      - .. .. .. 19.16 20.31 Flagyl S [SW]
  - metronidazole 500 mg suppository, 10
    - 1642K
      - .. .. .. 23.50 24.65 Flagyl S [SW]
  - metronidazole 500 mg suppository, 10
    - 5157K
      - .. .. .. 23.50 24.65 Flagyl S [SW]

- **METRONIDAZOLE**
  - Restricted benefit
  - Infection
    - Clinical criteria:
      - The condition must be due to anaerobic bacteria.

<table>
<thead>
<tr>
<th>metronidazole 400 mg tablet, 21</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1621H</td>
<td>* Metrogyl 400 [AF]</td>
</tr>
<tr>
<td></td>
<td>* Metronide 400 [AV]</td>
</tr>
<tr>
<td></td>
<td>2.30 12.49 11.34 * Flagyl [SW]</td>
</tr>
</tbody>
</table>
### Metronidazole

#### Restricted benefit
Acute anaerobic sepsis

**Treatment criteria:**
Must be treated in a hospital.

**Note**
Pharmaceutical benefits that have the form metronidazole 500 mg/100 mL (0.5%) injection, 10 x 100 mL bags and pharmaceutical benefits that have the form metronidazole 500 mg/100 mL (0.5%) injection, 5 x 100 mL bags are equivalent for the purposes of substitution.

### Tinidazole

#### Tinidazole 500 mg tablet, 4

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<tr>
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<td></td>
<td>5.41</td>
<td>16.54</td>
<td>Fasigyn [PF]</td>
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</table>

**Nitrofuran derivatives**

### Nitrofurantoin

#### Caution
Nitrofurantoin may cause peripheral neuritis and severe pulmonary reactions.

#### Nitrofurantoin 100 mg capsule, 30

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
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<tbody>
<tr>
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<td>30.94</td>
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#### Nitrofurantoin 50 mg capsule, 30

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</table>
**Other antibacterials**

- **HEXAMINE HIPPURATE**
  hexamine hippurate 1 g tablet, 100

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<tr>
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<td>Hiprex [IA]</td>
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</table>

**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.

**fluconazole 100 mg capsule, 28**

<table>
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<tbody>
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<td>APO-Fluconazole [TX]</td>
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</tbody>
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**fluconazole 100 mg/50 mL injection, 1 x 50 mL vial**

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**fluconazole 200 mg capsule, 28**

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<td>1475P</td>
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**fluconazole 200 mg/100 mL injection, 1 x 100 mL vial**

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<td>1474N</td>
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<td>APO-Fluconazole [TX]</td>
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**fluconazole 400 mg/200 mL injection, 1 x 200 mL bag**

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<td>APO-Fluconazole [TX]</td>
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**fluconazole 50 mg capsule, 28**

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<td>APO-Fluconazole [TX]</td>
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</table>
ANTIINFECTIVES FOR SYSTEMIC USE

**FLUCONAZOLE**

**Authority required**
- Treatment of cryptococcal meningitis in a patient unable to take a solid dose form of fluconazole
- 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
- Treatment of oesophageal candidiasis in an immunosuppressed patient unable to take a solid dose form of fluconazole
- Prophylaxis of oropharyngeal candidiasis in an immunosuppressed patient unable to take a solid dose form of fluconazole
- Treatment of serious and life-threatening candida infections in a patient unable to take a solid dose form of fluconazole

**Note**

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

Fluconazole 50 mg/5 mL oral liquid: powder for, 35 mL

<table>
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<tr>
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<td>..</td>
<td>#68.28</td>
<td>37.70</td>
<td>Diffucan [PF]</td>
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**ITRACONAZOLE**

**Authority required (STREAMLINED)**
- Systemic aspergillosis
- Systemic sporotrichosis
- Systemic histoplasmosis

**Authority required (STREAMLINED)**
- Treatment and maintenance therapy in patients with AIDS who have disseminated pulmonary histoplasmosis infection
- Treatment and maintenance therapy in patients with AIDS who have chronic pulmonary histoplasmosis infection
- Treatment of oropharyngeal candidiasis in immunosuppressed patients
- 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.

Itraconazole 100 mg capsule, 60

<table>
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<td>Sporanox [JC]</td>
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**POSACONAZOLE**

**Authority required**
- Treatment of invasive aspergillosis in patients intolerant to, or with disease refractory to, alternative therapy
- Treatment of fusariosis, zygomycosis, coccidioidomycosis, chromoblastomycosis and mycetoma in patients intolerant to, or with disease refractory to, alternative therapy
- Prophylaxis of invasive fungal infections, including both yeasts and moulds, in a patient who is at high risk of developing these infections, defined as follows:
(1) Neutropenia
Patients with anticipated neutropenia (an absolute neutrophil count of less than 500 cells per cubic millimetre) for at least 10 days, who are receiving chemotherapy for acute myelogenous leukaemia or myelodysplastic syndrome.
Treatment should continue until recovery of the neutrophil count to at least 500 cells per cubic millimetre.
Patients who have had a previous invasive fungal infection should have secondary prophylaxis during subsequent episodes of neutropenia.

(2) Graft versus host disease (GVHD)
Patients with acute GVHD grades II to IV or extensive chronic GVHD, who are receiving intensive immunosuppressive therapy after allogeneic haematopoietic stem cell transplant.
No more than 6 months therapy per episode will be PBS-subsidised

Note
Application for an increased maximum quantity to allow for up to 1 month's treatment and repeats sufficient for up to 6 months' treatment may be authorised.

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.

posaconazole 40 mg/mL oral liquid, 105 mL

- **VORICONAZOLE**
  - **Authority required**
  - Prophylaxis of invasive fungal infections including both yeasts and moulds

  **Clinical criteria:**
  Patient must be considered at high risk of developing an invasive fungal infection due to anticipated neutropenia (an absolute neutrophil count less than 500 cells per cubic millimetre) for at least 10 days whilst receiving chemotherapy for acute myeloid leukaemia or myelodysplastic syndrome; OR
  Patient must be considered at high risk of developing an invasive fungal infection due to having acute graft versus host disease (GVHD) grade II, III or IV, or, extensive chronic GVHD, whilst receiving intensive immunosuppressive therapy after allogeneic haematopoietic stem cell transplant; OR
  Patient must be undergoing allogeneic haematopoietic stem cell transplant using either bone marrow from an unrelated donor or umbilical cord blood (related or unrelated), and, be considered to be at high risk of developing an invasive fungal infection during the neutropenic phase prior to engraftment.

  **Note**
  For patients with graft versus host disease, acute myeloid leukaemia or myelodysplastic syndrome, applications 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.
  For patients undergoing allogeneic haematopoietic stem cell transplant, applications for an increased maximum quantity to allow for up to 1 month's treatment and repeats sufficient for up to 2 months' treatment 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.

voriconazole 200 mg tablet, 56

- **VORICONAZOLE**
  - **Authority required**
  - Definite or probable invasive aspergillosis

  **Treatment Phase:** Treatment and maintenance therapy

  **Population criteria:**
  Patient must be immunocompromised.

  **Authority required**
  Serious fungal infections
ANTIIINFECTIVES FOR SYSTEMIC USE

- **VORICONAZOLE**
  
  Authority required
  Definite or probable invasive aspergillosis
  Treatment Phase: Treatment and maintenance therapy
  
  Population criteria:
  Patient must be immunocompromised.
  
  Authority required
  Serious fungal infections
  Treatment Phase: Treatment and maintenance therapy
  
  Clinical criteria:
  The condition must be caused by Scedosporium species or Fusarium species.
  
  Authority required
  Serious Candida infections
  Treatment Phase: Treatment and maintenance therapy
  
  Clinical criteria:
  The condition must be caused by species not susceptible to fluconazole; OR
  The condition must be resistant to fluconazole; OR
  Patient must not tolerate fluconazole.

  Authority required
  Serious invasive mycosis infections
  Treatment Phase: Treatment and maintenance therapy
  
  Clinical criteria:
  The treatment must be for invasive mycosis infections other than definite or probable invasive aspergillosis.

  Note
  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.

  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.
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.

isoniazid 100 mg tablet, 100

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DRUGS FOR TREATMENT OF LEPROA

Drugs for treatment of leproa

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.

dapsone 100 mg tablet, 100

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dapsone 25 mg tablet, 100

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RIFAMPICIN

Authority required
Leprosy in adults

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.

rifampicin 150 mg capsule, 100

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rifampicin 300 mg capsule, 100

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RIFAMPICIN

Restricted benefit
Prophylaxis of meningococcal disease in close contacts and carriers

Restricted benefit
Prophylactic treatment of contacts of patients with Haemophilus influenzae type B

Note
Shared Care Model:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.
### ANTIVIRALS FOR SYSTEMIC USE

#### DIRECT ACTING ANTIVIRALS

**Nucleosides and nucleotides excl. reverse transcriptase inhibitors**

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<th>Item Code</th>
<th>Description</th>
<th>Authority</th>
<th>Code</th>
<th>Purpose</th>
<th>Maximum Quantity</th>
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<tr>
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<td>Aciclovir</td>
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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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<td>* Chem mart Aciclovir [CH]</td>
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<td>3632</td>
<td>Aciclovir</td>
<td>Authority required (STREAMLINED)</td>
<td>3632</td>
<td>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</td>
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#### ACICLOVIR

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ANTIINFECTIVES FOR SYSTEMIC USE

- **ACICLOVIR**

  **Authority required (STREAMLINED)**

  **3622**
  Treatment of patients with herpes zoster within 72 hours of the onset of the rash

  **Authority required (STREAMLINED)**

  **3631**
  Herpes zoster ophthalmicus

  **Note**
  Aciclovir is effective only if commenced within 72 hours of onset of rash.

  Aciclovir 800 mg is not PBS-subsidised for herpes simplex or chickenpox.

  No applications for repeats will be authorised.

  **aciclovir 800 mg tablet, 35**

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- **FAMCICLOVIR**

  **Authority required (STREAMLINED)**

  **3624**
  Episodic treatment of moderate to severe recurrent genital herpes. Microbiological confirmation of diagnosis (viral culture, antigen detection or nucleic acid amplification by PCR) is required but need not delay treatment

  **Note**
  Famciclovir 250 mg is not PBS-subsidised for chickenpox or herpes simplex infections other than genital herpes.

  **famciclovir 250 mg tablet, 20**

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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.

  **famciclovir 250 mg tablet, 56**

<table>
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<td>** Ezovir [AF]**</td>
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ANTIINFECTIVES FOR SYSTEMIC USE

FAMCICLOVIR

Authority required (STREAMLINED)

3622
Treatment of patients with herpes zoster within 72 hours of the onset of the rash

Note
Famiclovir is effective only if commenced within 72 hours of onset of rash.
Famiclovir 250 mg is not PBS-subsidised for chickenpox or herpes simplex infections other than genital herpes.
No applications for repeats will be authorised.

famciclovir 250 mg tablet, 21

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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
Famiclovir is effective only if commenced within 72 hours of onset of rash.
Famiclovir 500 mg is not PBS-subsidised for chickenpox.
Famiclovir 500 mg is not PBS-subsidised for herpes zoster, genital herpes or other herpes simplex infections in immunocompetent patients.
No applications for repeats will be authorised.

famciclovir 500 mg tablet, 30

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<td></td>
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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
Famiclovir 500 mg is not PBS-subsidised for chickenpox.
Famiclovir 500 mg is not PBS-subsidised for herpes zoster, genital herpes or other herpes simplex infections in immunocompetent patients.
ANTIINFECTIVES FOR SYSTEMIC USE

famciclovir 500 mg tablet, 56

<table>
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VALACICLOVIR

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

Valaciclovir 500 mg is not PBS-subsidised for chickenpox or herpes simplex infections other than genital herpes.

valaciclovir 500 mg tablet, 30

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<td>* Valaciclovir RBX [RA]</td>
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<td>* Valacor 500 [CR]</td>
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<td></td>
<td>* Valnir [QA]</td>
<td>* Valtrex [AS]</td>
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<td></td>
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VALACICLOVIR

Authority required (STREAMLINED)

3624

Episodic treatment of moderate to severe recurrent genital herpes. Microbiological confirmation of diagnosis (viral culture, antigen detection or nucleic acid amplification by PCR) is required but need not delay treatment

Note

Valaciclovir 500 mg is not PBS-subsidised for chickenpox or herpes simplex infections other than genital herpes.

valaciclovir 500 mg tablet, 30

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<td>* Terry White Chemists Valaciclovir [TW]</td>
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<td></td>
<td></td>
<td>* Vaclovir [AF]</td>
<td>* Valaciclovir Actavis [VN]</td>
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<td>* Valaciclovir GA [GN]</td>
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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. No applications for increased maximum quantities and/or repeats will be authorised.

valaciclovir 500 mg tablet, 10

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<td>* Valaciclovir GA [GN]</td>
<td>* Valaciclovir Sandoz [SZ]</td>
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<td></td>
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<td>* Valnir [QA]</td>
<td>* Valtrex [AS]</td>
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220

ANTIINFECTIVES FOR SYSTEMIC USE
ANTIINFECTIVES FOR SYSTEMIC USE

* Zelitrex [UA]

### VALACICLOVIR

**Authority required (STREAMLINED)** 3622
Treatment of patients with herpes zoster within 72 hours of the onset of the rash

**Authority required (STREAMLINED)** 3631
Herpes zoster ophthalmicus

**Note**
Valaciclovir is effective only if commenced within 72 hours of onset of rash.
Valaciclovir 500 mg is not PBS-subsidised for chickenpox or herpes simplex infections other than genital herpes.
No applications for repeats will be authorised.

Valaciclovir 500 mg tablet, 42

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### VACCINES

#### BACTERIAL VACCINES

**Pneumococcal vaccines**

#### PNEUMOCOCCCAL PURIFIED CAPSULAR POLYSACCHARIDES

**Restricted benefit**
Splenectomised persons over 2 years of age

**Restricted benefit**
Persons with Hodgkin's disease

**Restricted benefit**
Persons at high risk of pneumococcal infections

Pneumococcal purified capsular polysaccharides 25 microgram/0.5 mL injection, 1 x 0.5 mL syringe

<table>
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<td>49.02</td>
<td>37.70</td>
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<td>Pneumovax 23 [CS]</td>
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Pneumococcal purified capsular polysaccharides 25 microgram/0.5 mL injection, 1 x 0.5 mL vial

<table>
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<th>Packs</th>
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<th>MRVSN $</th>
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<td>49.02</td>
<td>37.70</td>
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<td>Pneumovax 23 [CS]</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.

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

<table>
<thead>
<tr>
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<th>Packs</th>
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<td>144.59</td>
<td>37.70</td>
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<td>MassBiologics tetanus and diphtheria toxoids adsorbed [CS]</td>
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diphtheria toxoid 2 international units/0.5 mL + tetanus toxoid 20 international units/0.5 mL injection, 5 x 0.5 mL syringes

<table>
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<th>Packs</th>
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### ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

#### ANTINEOPLASTIC AGENTS

#### ALKYLATING AGENTS

**Nitrogen mustard analogues**

- **CHLORAMBUCIL**
  - chlorambucil 2 mg tablet, 25
  - 1163F

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<td>154.12</td>
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- **CYCLOPHOSPHAMIDE**
  - cyclophosphamide 50 mg tablet, 50
  - 10026Q

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<td>83.64</td>
<td>37.70</td>
<td>Endoxan [BX]</td>
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- **MELPHALAN**
  - melphalan 2 mg tablet, 25
  - 2547C

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<td>77.11</td>
<td>37.70</td>
<td>Alkeran [AS]</td>
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**Alkyl sulfonates**

- **BUSULFAN**
  - busulfan 2 mg tablet, 100
  - 1128J

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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.

<table>
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<td>17539.66</td>
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**Other alkylating agents**

- **TEMOZOLOMIDE**
  - temozolomide 100 mg capsule, 5
  - 8380C

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- temozolomide 140 mg capsule, 5
  - 9362R

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- temozolomide 180 mg capsule, 5
  - 2438H

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ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS
### TEMOZOLOMIDE

**Restricted benefit**

Glioblastoma multiforme

**Treatment criteria:**

Patient must be undergoing concomitant radiotherapy.

**Note**

Temozolomide is not PBS-subsidised for use in conjunction with PBS-subsidised carmustine. No increase in the maximum number of repeats may be authorised.

#### Temozolomide 20 mg capsule, 5

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<td><em>Temozolomide AN [EA]</em></td>
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#### Temozolomide 250 mg capsule, 5

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#### Temozolomide 5 mg capsule, 5

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#### Temozolomide 100 mg capsule, 5

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#### Temozolomide 140 mg capsule, 5

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#### Temozolomide 180 mg capsule, 5

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<td>1766.53</td>
<td>37.70</td>
<td><em>Astromide [GN]</em></td>
<td><em>Orion Temozolomide [ON]</em></td>
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<tr>
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<td><em>Temodal [MK]</em></td>
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#### Temozolomide 20 mg capsule, 5

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<td><em>Temizole 20 [QA]</em></td>
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<td></td>
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<td><em>Temozolomide Alphapharm [AF]</em></td>
<td><em>Temozolomide AN [EA]</em></td>
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#### Temozolomide 5 mg capsule, 5

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<td><em>Temozolomide AN [EA]</em></td>
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### ANTIMETABOLITES

- **Folic acid analogues**

Schedule of Pharmaceutical Benefits
## ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

### METHOTREXATE

**methotrexate 10 mg tablet, 15**

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<th>Max Qty Packs</th>
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**methotrexate 2.5 mg tablet, 30**

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<td>13.46</td>
<td>14.61</td>
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**methotrexate 5 mg/2 mL injection, 5 x 2 mL vials**

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**methotrexate 10 mg tablet, 50**

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**methotrexate 50 mg/2 mL injection, 5 x 2 mL vials**

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<td>19.69</td>
<td>20.84</td>
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### FLUDARABINE

**fludarabine phosphate 10 mg tablet, 20**

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<td>937.04</td>
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### MERCAPTOPURINE

**mercaptopurine 20 mg/mL oral liquid, 100 mL**

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**mercaptopurine 50 mg tablet, 25**

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<td>*267.12</td>
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### THIOGUANINE

**thioguanine 40 mg tablet, 25**

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<tr>
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<td>243.21</td>
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### CAPECITABINE

**capecitabine 150 mg tablet, 60**

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<tr>
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<td>105.47</td>
<td>37.70</td>
<td>* Capecitabine Actavis [GN]</td>
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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.
### 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.
  - **Locally advanced or metastatic non-small cell lung cancer**

- **VINORELBINE 20 mg capsule, 1**

- **VINORELBINE 30 mg capsule, 1**

- **Podophyllotoxin derivatives**

- **ETOPOSIDE**

- **ETOPOSIDE 100 mg capsule, 10**

- **ETOPOSIDE 50 mg capsule, 20**

### CYTOTOXIC ANTIBIOTICS AND RELATED SUBSTANCES

**Anthracyclines and related substances**

- **IDARUBICIN**
  - **Restricted benefit**
  - Acute myelogenous leukaemia

- **IDARUBICIN hydrochloride 10 mg capsule, 1**

- **IDARUBICIN hydrochloride 5 mg capsule, 1**

### OTHER ANTINEOPLASTIC AGENTS

**Protein kinase inhibitors**

- **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**
**ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS**

**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.

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

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

Special Pricing Arrangements apply.

---

**dabrafenib 50 mg capsule, 120**

<table>
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<tr>
<th>Max Qty Packs</th>
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**dabrafenib 75 mg capsule, 120**

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<td>8758.87</td>
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<td>Tafinlar [GK]</td>
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---

**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.

A patient who has had progressive disease when treated with another BRAF inhibitor is not eligible to receive PBS-subsidised treatment with this drug.

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

**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
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 reasons 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.
ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

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.

### 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% 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 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
3. 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.
Antineoplastic and Immunomodulating Agents

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 in the blood, to dasatinib in the preceding 18 months and thereafter at 12 month intervals.

Applications for authorisation must be in writing and must include:

1. A completed authority prescription form; and
2. A completed Chronic Myeloid Leukaemia - Second and Third Line - Application Form for continuing treatment; and
3. Demonstration of continued response to treatment as evidenced by either:
   a. Major cytogenetic response [see Note explaining definitions of response]. Where this has been supplied within the previous 12 months (or 18 months for the initial supply), only the date of the relevant pathology report needs to be provided; or
   b. A peripheral blood level of BCR-ABL of less than 1% on the international scale [see Note explaining definitions of response]. Where this has been supplied within the previous 12 months (or 18 months for the initial supply), only the date of the relevant pathology report needs to be provided.

Note

Any queries concerning the arrangements to prescribe dasatinib may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of tyrosine kinase inhibitors (TKI) agents for all phases of chronic myeloid leukaemia. Where the term TKI agent appears in the following notes and restrictions it refers to dasatinib or nilotinib. Imatinib mesylate is not approved for use in second or third line treatment.

Patients are eligible for PBS-subsidised treatment with only one of dasatinib or nilotinib at any one time and must not be receiving concomitant interferon alfa therapy. Eligible patients may only swap between these agents if they have not failed prior PBS-subsidised treatment with that agent.

Nilotinib is not approved for patients in blast crisis.

1. Initial second line treatment

From 1 April 2012, under the PBS, a patient will be able to be prescribed either dasatinib or nilotinib within the initial 18 month treatment period as second-line therapy, as long as only one agent is approved at a time and providing the patient did not fail that drug as first-line therapy.

During the initial 18 month treatment period, switching between approved second-line agents may only occur for reasons of intolerance, not failure of response.

2. Initial third line treatment

Third-line treatment with a TKI can only be approved when imatinib is used for first-line treatment. Patients will only be approved for PBS-subsidised treatment with one third-line agent.

From 1 April 2012, under the PBS, a patient will be able to be prescribed either dasatinib or nilotinib providing the patient did not fail that drug as first or second line therapy and for nilotinib the patient is not in blast crisis.

3. Continuing treatment for second and third line treatment

All continuing applications are to be written and must include a pathology report demonstrating the patient has responded to PBS-subsidised treatment as follows:

(i) within 18 months of the commencement of treatment, at which time patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% has been demonstrated may receive authorisation for a further 12 months of treatment; and
(ii) at no greater than 12 month intervals thereafter, to demonstrate that the major cytogenetic response or peripheral blood BCR-ABL level of less than 1% has been sustained.

During second line continuing treatment beyond the initial 18 month treatment period, switching between approved second line TKI agents may only occur for reason of intolerance. Where there is failure of response, switching may only occur through application for prescription of a third line agent.

4. Authority approval requirements.

Response criteria to initial treatment with dasatinib or nilotinib:

For the purposes of assessing response to PBS-subsidised treatment with dasatinib or nilotinib, either cytogenetic analysis indicating the number of Philadelphia positive [t (9;22)] cells in the bone marrow measured by standard karyotyping, or quantitative PCR indicating the relative level of BCR-ABL transcript in the peripheral blood using the international scale, must be submitted. For bone marrow analyses, where the standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe must be submitted. The cytogenetic or peripheral blood quantitative PCR analyses must be submitted within 18 months of the commencement of treatment with dasatinib or nilotinib (patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% is demonstrable by 18 months are eligible to receive continuing treatment with that agent).

5. Definitions of response.

A major cytogenetic response is defined as less than 35% Philadelphia positive bone marrow cells.

A peripheral blood BCR-ABL level of less than 1% on the international scale (Blood 108: 28-37, 2006) also indicates a response, at least the biological equivalent of a major cytogenetic response.

Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing tyrosine kinase inhibitor (TKI) therapy.

Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing tyrosine kinase inhibitor therapy.

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**DASATINIB**

**Authority required**

Initial treatment, as monotherapy, of a patient with acute lymphoblastic leukaemia (ALL) bearing the Philadelphia chromosome or expressing the transcript, BCR-ABL, who has failed treatment with chemotherapy AND imatinib and where appropriate, allogeneic haemopoietic stem cell transplantation.

Failure of treatment is defined as either:

(i) Failure to achieve a complete morphological and cytogenetic remission after a minimum of 2 months treatment with intensive chemotherapy and imatinib;

(ii) Morphological or cytogenetic relapse of leukaemia after achieving a complete remission induced by chemotherapy and imatinib;

(iii) Morphological or cytogenetic relapse or persistence of leukaemia after allogeneic haemopoietic stem cell transplantation.

Patients must have active leukaemia, as defined by presence on current pathology assessments of either morphological infiltration of the bone marrow (greater than 5% lymphoblasts) or cerebrospinal fluid or other sites; OR the presence of cells bearing the Philadelphia chromosome on cytogenetic or FISH analysis in the bone marrow of patients in morphological remission.

The first authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Acute Lymphoblastic Leukaemia Dasatinib PBS Authority Application - Supporting Information Form; and

(c) a signed patient acknowledgement; and

(d) a pathology report demonstrating that the patient has active acute lymphoblastic leukaemia, either manifest as cytogenetic evidence of the Philadelphia chromosome, or morphological evidence of acute lymphoblastic leukaemia plus qualitative RT-PCR evidence of BCR-ABL transcript. The date of the relevant pathology report(s) need(s) to be provided.

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

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### EROTONIB

**Authority required**
Stage IIIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)
Treatment Phase: Continuing treatment

**Clinical criteria:**
The treatment must be as monotherapy, AND
Patient must have previously been issued with an authority prescription for this drug prior to 1 August 2014, AND
Patient must not have progressive disease.

**Population criteria:**
Patient must have a wild type epidermal growth factor receptor (EGFR) gene; OR
Patient must have an epidermal growth factor receptor (EGFR) gene of unknown type.

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### EROTONIB

**Authority required**
Stage IIIIB (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 IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)
Treatment Phase: Continuing treatment

**Clinical criteria:**
The treatment must be as monotherapy, **AND**
Patient must have previously been issued with an authority prescription for this drug, **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.

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**everolimus 100 mg tablet, 30**

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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.

**Authority required**
Tuberous sclerosis complex (TSC)
Treatment Phase: Continuing treatment

**Clinical criteria:**
The condition must be subependymal giant cell astrocytomas (SEGAs) associated with TSC; **OR**
The condition must be visceral tumours associated with TSC, **AND**
The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
Patient must have previously been treated with PBS-subsidised everolimus for this condition, **AND**
Patient must have demonstrated a response to prior treatment.

**Note**
Special Pricing Arrangements apply.

**everolimus 2.5 mg tablet, 30**

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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.

**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.

**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 not be pre-menopausal.

**Note**
Patients who have progressive disease with everolimus are no longer eligible for PBS-subsidised everolimus.

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.

**Authority required**
Metastatic or unresectable, well-differentiated malignant pancreatic neuroendocrine tumour (pNET)

**Treatment Phase:** Continuing treatment

**Clinical criteria:**
Patient must have previously been issued with an authority prescription for this drug, **AND**
Patient must not have disease progression, **AND**
The treatment must be as monotherapy.

Patients who have progressive disease with this drug are no longer eligible for PBS-subsidised treatment with this drug.

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

Special Pricing Arrangements apply.

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### EVEROLIMUS

**Authority required**
Stage IV clear cell variant renal cell carcinoma (RCC)

**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.

**Authority required**
Metastatic or unresectable, well-differentiated malignant pancreatic neuroendocrine tumour (pNET)

**Clinical criteria:**
- Patient must be symptomatic (despite somatostatin analogues); OR
- Patient must have disease progression, **AND**
- The treatment must be as monotherapy.
- Disease progression must be documented in the patient's medical records.
- Patients who have developed progressive disease on sunitinib are not eligible to receive PBS-subsidised everolimus.
- Patients who have developed intolerance to sunitinib of a severity necessitating permanent treatment withdrawal are eligible to receive PBS-subsidised everolimus.

**Note**
- No increase in the maximum quantity or number of units may be authorised.
- No increase in the maximum number of repeats may be authorised.
- Special Pricing Arrangements apply.

### GEFITINIB

**Authority required**
Stage IIIIB (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 IIIIB (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.

**gefitinib 250 mg tablet, 30**

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### 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
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.

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 level 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).

6. 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.

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.

**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.

No applications for increased repeats will be authorised.

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**IMATINIB**

**Authority required**

Initial PBS-subsidised treatment of a patient with hypereosinophilic syndrome or chronic eosinophilic leukaemia requiring treatment and confirmed to carry the FIP1L1-PDGFRA fusion gene.

Maximum dose: 400 mg per day.

Applications for authorisation for initial treatment must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Rare Diseases Imatinib PBS Authority Application - Supporting Information Form; and
(c) a copy of the pathology report confirming the presence of the FIP1L1-PDGFRA fusion gene; and
(d) a copy of the full blood examination report confirming the presence of hypereosinophilic syndrome or chronic eosinophilic leukaemia; and
(e) details of organ involvement requiring treatment, including a copy of the radiology, nuclear medicine, respiratory function or anatomical pathology reports as appropriate; and
(f) a signed patient acknowledgement

**Authority required**

Continuing PBS-subsidised treatment of a patient with hypereosinophilic syndrome or chronic eosinophilic leukaemia who has previously been issued with an authority prescription for imatinib and who has achieved and maintained a complete haematological response.

Maximum dose: 400 mg per day.

Applications for authorisation must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Rare Diseases Imatinib PBS Authority Application - Supporting Information Form; and
(c) a copy of the full blood examination report which demonstrates a complete haematological response, with a normal eosinophil count; and
(d) a statement that the disease has not progressed on imatinib therapy.

**Note**

Any queries concerning the arrangements to prescribe imatinib mesylate may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe imatinib mesylate should be forwarded to:
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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.
No applications for increased repeats will be authorised.

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### IMATINIB

**Authority required**

Initial PBS-subsidised treatment of a patient with a myelodysplastic or myeloproliferative disorder where:
1. there is confirmed evidence of a platelet-derived growth factor receptor (PDGFR) gene re-arrangement either by standard karyotyping, or FISH or PDGFRB fusion gene transcript; and
2. the patient has previously failed an adequate trial of one or more of the following conventional therapies:
   - cytarabine;
   - etoposide;
   - hydroxyurea.

Maximum dose: 400 mg per day.

Applications for authorisation for initial treatment must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Rare Diseases Imatinib PBS Authority Application - Supporting Information Form; and
(c) a copy of the pathology report confirming the platelet-derived growth factor receptor (PDGFR) gene re-arrangement; and
(d) a copy of the bone marrow biopsy report which demonstrates the presence of a myelodysplastic or myeloproliferative disorder; and
(e) details of the prior therapy trialled and the response; and
(f) a signed patient acknowledgement.

**Authority required**

Continuing PBS-subsidised treatment of a patient with a PDGFRB fusion gene-positive myelodysplastic or myeloproliferative disorder who has previously been issued with an authority prescription for imatinib and who has demonstrated a complete haematological response.

Maximum dose: 400 mg per day.

Applications for authorisation must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Rare Diseases Imatinib PBS Authority Application - Supporting Information Form; and
(c) a copy of the full blood examination report which demonstrates a complete haematological response; and
(d) a statement that the disease has not progressed on imatinib therapy.

**Note**

Any queries concerning the arrangements to prescribe imatinib mesylate may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe imatinib mesylate should be forwarded to:
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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.
No applications for increased repeats will be authorised.

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**IMATINIB**

**Authority required**

Initial PBS-subsidised treatment of a patient with aggressive systemic mastocytosis with eosinophilia where:

1. there is confirmed evidence of the FIP1L1-PDGFRα fusion gene; and
2. the patient has previously failed an adequate trial of one or more of the following conventional therapies:
   - corticosteroids;
   - hydroxyurea.

Maximum dose: 400 mg per day.

Applications for authorisation for initial treatment must be made in writing and must include:

(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 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.

No applications for increased repeats will be authorised.

**imatinib 100 mg tablet, 60**

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antineoplastic and immunomodulating agents

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
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.

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.)

no applications for increased repeats will be authorised.

imatinib

100 mg tablet, 60

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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
Any queries concerning patients who are enrolled on the Imatinib Compassionate Program may be directed to the Department of Human Services on 1800 700 270.

Authority required
Gastrointestinal stromal tumour
Treatment Phase: Continuing treatment
Clinical criteria:
The treatment must be adjuvant to complete surgical resection of primary gastrointestinal stromal tumour (GIST), AND
Patient must be at high risk of recurrence following complete surgical resection of primary GIST, AND
The treatment must not exceed a dose of 400 mg per day for a period of 36 months in total (initial plus continuing therapy), AND
Patient must have previously been issued with an authority prescription for imatinib for adjuvant treatment following complete resection of primary GIST.
Applications for continuing therapy may be made by telephone.

Note
Authority approval for continuing treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
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

■ 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
General

(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:
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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.

No applications for increased repeats will be authorised.

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**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 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
(c) 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 9026
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.

**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.
Note

Any queries concerning the arrangements to prescribe lapatinib may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Lapatinib should not be used in patients with a left ventricular ejection fraction (LVEF) of less than 45% or with symptomatic heart failure. Cardiac function must be tested by a suitable method including, for example, ECHO or MUGA, prior to seeking the initial authority approval and then at 3 monthly intervals during treatment.

Lapatinib is not PBS-subsidised when used in combination with Commonwealth-subsidised trastuzumab.

If disease progression occurs, the prescribing doctor must contact Medicare Australia within one week on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) and lapatinib treatment must be ceased immediately.

If treatment with a taxane is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of the accepted toxicities, including severity, can be found on the Medicare Australia website [www.medicareaustralia.gov.au].

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

Lapatinib 250 mg tablet, 70

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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

HOBART TAS 7001
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, 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 reasons 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.

**NILOTINIB** Capsule 150 mg (as hydrochloride monohydrate), 120

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**NILOTINIB**

**Authority required**

Initial treatment, as the sole PBS-subsidised therapy, of a patient with chronic myeloid leukaemia in chronic or accelerated phase who has failed an adequate trial of imatinib or dasatinib as first-line treatment.

Failure of an adequate trial of imatinib or dasatinib is defined as:

1. Lack of response to initial imatinib or dasatinib therapy, defined as either:
   - failure to achieve a haematological response after a minimum of 3 months therapy with imatinib or dasatinib for patients initially treated in chronic phase; or
   - failure to achieve any cytogenetic response after a minimum of 6 months therapy with imatinib or dasatinib for patients initially treated in chronic phase as demonstrated on bone marrow biopsy by presence of greater than 95% Philadelphia chromosome positive cells; or
— failure to achieve a major cytogenetic response or a peripheral blood BCR-ABL level of less than 1% after a minimum of 12 months therapy with imatinib or dasatinib; OR
(ii) Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing imatinib or dasatinib therapy; OR
(iii) Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing imatinib or dasatinib therapy; OR
(iv) Development of accelerated phase in a patient previously prescribed imatinib or dasatinib for the chronic phase of chronic myeloid leukaemia.

Accelerated phase is defined by the presence of 1 or more of the following:
(1) Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 15% but less than 30%; or
(2) Percentage of blasts plus promyelocytes in the peripheral blood or bone marrow greater than or equal to 30%, provided that blast count is less than 30%; or
(3) Peripheral basophils greater than or equal to 20%; or
(4) Progressive splenomegaly to a size greater than or equal to 10 cm below the left costal margin to be confirmed on 2 occasions at least 4 weeks apart, or a greater than or equal to 50% increase in size below the left costal margin over 4 weeks; or
(5) Karyotypic evolution (chromosomal abnormalities in addition to a single Philadelphia chromosome); OR
(v) Disease progression (defined as a greater than or equal to 50% increase in peripheral white blood cell count, blast count, basophils or platelets) during first-line imatinib or dasatinib therapy in patients with accelerated phase chronic myeloid leukaemia, provided that blast crisis has been excluded on bone marrow biopsy.

Patients should be commenced on a dose of nilotinib of 400 mg twice daily. Continuing therapy is dependent on patients demonstrating a major cytogenetic response to nilotinib therapy or a peripheral blood BCR-ABL level of less than 1% within 18 months and thereafter at 12 monthly intervals.

Applications for authorisation must be in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Chronic Myeloid Leukaemia - Second and Third Line - Supporting Information Form; and
(c) a signed patient acknowledgement; and
(d) a bone marrow biopsy pathology report demonstrating the patient has active chronic myeloid leukaemia, either manifest as cytogenetic evidence of the Philadelphia chromosome, or RT-PCR level of BCR-ABL transcript greater than 0.1% on the international scale. (The date of the relevant pathology report needs to be provided); and
(e) where there has been a loss of response to imatinib or dasatinib, a copy of the current confirming pathology report(s) from an Approved Pathology Authority or details of the dates of assessment in the case of progressive splenomegaly or extramedullary involvement

**Authority required**
Continuing treatment, as the sole PBS-subsidised therapy, of a patient who has received initial PBS-subsidised treatment with nilotinib for chronic myeloid leukaemia, and who has demonstrated either a major cytogenetic response, or less than 1% BCR-ABL level in the blood, to dasatinib in the 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, whereas 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.

NILOTINIB Capsule 200 mg (as hydrochloride monohydrate), 120

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**PAZOPANIB**

**Authority required**
Advanced (unresectable and/or metastatic) soft tissue sarcoma

**Treatment Phase:** Initial treatment

**Clinical criteria:**
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**
Antineoplastic and Immunomodulating Agents

No increase in the maximum quantity or number of units may be authorised.
No increase in the maximum number of repeats may be authorised.
Special Pricing Arrangements apply.

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### 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.
No increase in the maximum quantity or number of units may be authorised.
No increase in the maximum number of repeats may be authorised.
Special Pricing Arrangements apply.

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### PAZOPANIB

**Authority required**

Advanced (unresectable and/or metastatic) soft tissue sarcoma

**Clinical criteria:**

- Patient must have previously been issued with an authority prescription for pazopanib, **AND**
- Patient must have stable or responding disease according to the Response Evaluation Criteria In Solid Tumours (RECIST), **AND**
- Patient must require dose adjustment, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Applications for continuing therapy may be made by telephone.

**Note**

Response Evaluation Criteria In Solid Tumours (RECIST) is defined as follows:
- Complete response (CR) is disappearance of all target lesions.
- Partial response (PR) is a 30% decrease in the sum of the longest diameter of target lesions.
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No increase in the maximum number of repeats may be authorised.
Special Pricing Arrangements apply.
### Schedule of Pharmaceutical Benefits

#### PAZOPANIB

**Authority required**

Stage IV clear cell variant renal cell carcinoma (RCC)

**Clinical criteria:**
- Patient must have previously been issued with an authority prescription for pazopanib, **AND**
- Patient must have stable or responding disease according to the Response Evaluation Criteria In Solid Tumours (RECIST), **AND**
- Patient must require dose adjustment, **AND**
- The treatment must be the sole PBS-subsidised tyrosine kinase inhibitor therapy for this condition.

**Note**

Patients who have progressive disease with pazopanib are no longer eligible for PBS-subsidised pazopanib.

Patients who have progressive disease on sunitinib are not eligible to receive PBS-subsidised pazopanib.

Response Evaluation Criteria In Solid Tumours (RECIST) is defined as follows:
- Complete response (CR) is disappearance of all target lesions.
- Partial response (PR) is a 30% decrease in the sum of the longest diameter of target lesions.
- Progressive disease (PD) is a 20% increase in the sum of the longest diameter of target lesions.

Stable disease (SD) is small changes that do not meet above criteria.

Special Pricing Arrangements apply.

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### PAZOPANIB

**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 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.

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

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

Special Pricing Arrangements apply.

---

### PAZOPANIB

**Authority required**

Stage IV clear cell variant renal cell carcinoma (RCC)

**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.

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Stable disease (SD) is small changes that do not meet above criteria.

Special Pricing Arrangements apply.

---

### PAZOPANIB

**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**
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- Progressive disease (PD) is a 20% increase in the sum of the longest diameter of target lesions.

Stable disease (SD) is small changes that do not meet above criteria.

Special Pricing Arrangements apply.

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### PAZOPANIB

**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 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.

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

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

Special Pricing Arrangements apply.
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 on sunitinib are not eligible to receive PBS-subsidised pazopanib.

**Response Evaluation Criteria In Solid Tumours (RECIST) is defined as follows:**
- Complete response (CR) is disappearance of all target lesions.
- Partial response (PR) is a 30% decrease in the sum of the longest diameter of target lesions.
- Progressive disease (PD) is a 20% increase in the sum of the longest diameter of target lesions.

Stable disease (SD) is small changes that do not meet above criteria.

### Authority required
Stage IV clear cell variant renal cell carcinoma (RCC)
Treatment Phase: Initial treatment
**Clinical criteria:**
- Patient must have been receiving treatment with pazopanib prior to 1 October 2012, **AND**
- The treatment must be the sole PBS-subsidised tyrosine kinase inhibitor therapy for this condition.

**Note**
- Patients who have progressive disease with pazopanib are no longer eligible for PBS-subsidised pazopanib.

Special Pricing Arrangements apply.

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### SORAFENIB

**Authority required**
Stage IV clear cell variant renal cell carcinoma (RCC)
Treatment Phase: Initial treatment
**Clinical criteria:**
- Patient must have progressive disease according to the Response Evaluation Criteria In Solid Tumours (RECIST) following first-line treatment with a tyrosine kinase inhibitor, **AND**
- Patient must have a WHO performance status of 2 or less, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Patients who have developed intolerance to a tyrosine kinase inhibitor of a severity necessitating permanent treatment withdrawal are eligible to receive PBS-subsidised treatment with this drug.

A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.

**Note**
- Response Evaluation Criteria In Solid Tumours (RECIST) is defined as follows:
- Complete response (CR) is disappearance of all target lesions.
- Partial response (PR) is a 30% decrease in the sum of the longest diameter of target lesions.
- Progressive disease (PD) is a 20% increase in the sum of the longest diameter of target lesions.

Stable disease (SD) is small changes that do not meet above criteria.

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

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

Special Pricing Arrangements apply.

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### SORAFENIB

**Authority required**
Stage IV clear cell variant renal cell carcinoma (RCC)
Treatment Phase: Continuing treatment beyond 3 months
Clinical criteria:
Patient must have previously been issued with an authority prescription for this drug for this condition, **AND**
Patient must have stable or responding disease according to the Response Evaluation Criteria In Solid Tumours (RECIST), **AND**
The treatment must be the sole PBS-subsidised therapy for this condition.
A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.

**Note**
Response Evaluation Criteria In Solid Tumours (RECIST) is defined as follows:
- Complete response (CR) is disappearance of all target lesions.
- Partial response (PR) is a 30% decrease in the sum of the longest diameter of target lesions.
- Progressive disease (PD) is a 20% increase in the sum of the longest diameter of target lesions.

Stable disease (SD) is small changes that do not meet above criteria.
No increase in the maximum quantity or number of units may be authorised.
No increase in the maximum number of repeats may be authorised.
Special Pricing Arrangements apply.

### 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.
No increase in the maximum quantity or number of units may be authorised.
No increase in the maximum number of repeats may be authorised.
Special Pricing Arrangements apply.

### SUNITINIB

**Authority required**

Metastatic or unresectable, well-differentiated malignant pancreatic neuroendocrine tumour (pNET)
Treatment Phase: Initial treatment

Clinical criteria:
Patient must be symptomatic (despite somatostatin analogues); OR
Patient must have disease progression, **AND**
The treatment must be as monotherapy.
Disease progression must be documented in the patient's medical records.
Patients who have developed progressive disease on everolimus are not eligible to receive PBS-subsidised sunitinib for this condition.
Patients who have developed intolerance to everolimus of a severity necessitating permanent treatment withdrawal are eligible to receive PBS-subsidised sunitinib.

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

No increase in the maximum number of repeats may be authorised.
Special Pricing Arrangements apply.

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- **SUNITINIB**
  - **Authority required**
  - Metastatic or unresectable, well-differentiated malignant pancreatic neuroendocrine tumour (pNET)
  - Treatment Phase: Continuing treatment
  - **Clinical criteria:**
    - Patient must have previously been issued with an authority prescription for this drug, **AND**
    - Patient must not have disease progression, **AND**
    - The treatment must be as monotherapy.
    - Patients who have progressive disease with this drug are no longer eligible for PBS-subsidised treatment with this drug.
  - **Note**
    - No increase in the maximum quantity or number of units may be authorised.
    - No increase in the maximum number of repeats may be authorised.
    - Special Pricing Arrangements apply.

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- **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.
    - Patients who have developed progressive disease on pazopanib are not eligible to receive PBS-subsidised sunitinib.
    - Response Evaluation Criteria In Solid Tumours (RECIST) is defined as follows:
      - Complete response (CR) is disappearance of all target lesions.
      - Partial response (PR) is a 30% decrease in the sum of the longest diameter of target lesions.
      - Progressive disease (PD) is a 20% increase in the sum of the longest diameter of target lesions.
      - Stable disease (SD) is small changes that do not meet above criteria.
    - Special Pricing Arrangements apply.

sunitinib 12.5 mg capsule, 28

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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.

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

Special Pricing Arrangements apply.

---

### SUNITINIB

**Authority required**

Stage IV clear cell variant renal cell carcinoma (RCC)

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must meet the Memorial Sloan Kettering Cancer Centre (MSKCC) low to intermediate risk group criteria, **AND**

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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.
- No increase in the maximum quantity or number of units may be authorised.
- No increase in the maximum number of repeats may be authorised.
- Special Pricing Arrangements apply.

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### Other antineoplastic agents

#### HYDROXYUREA

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### ENDOCRINE THERAPY

#### HORMONES AND RELATED AGENTS

**Progestogens**

#### MEDROXYPROGESTERONE

- **Restricted benefit**
  - Hormone-dependent advanced breast cancer

**medroxyprogesterone acetate 500 mg tablet, 30**

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#### MEDROXYPROGESTERONE

- **Restricted benefit**
  - Hormone-dependent breast cancer
  - **Restricted benefit**
  - Endometrial cancer

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#### MEGESTROL

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Gonadotropin releasing hormone analogues

- **GOSERELIN**

  **Restricted benefit**
  Carcinoma of the prostate
  
  **Clinical criteria:**
  The condition must be locally advanced (stage C); OR
  The condition must be metastatic (stage D).

  **goserelin 10.8 mg implant, 1**

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- **GOSERELIN**

  **Restricted benefit**
  Carcinoma of the prostate
  
  **Clinical criteria:**
  The condition must be locally advanced (stage C); OR
  The condition must be metastatic (stage D).

  **Restricted benefit**
  Breast cancer
  
  **Clinical criteria:**
  The condition must be locally advanced (stage III); OR
  The condition must be metastatic (stage IV), AND
  The condition must be hormone receptor positive.

  **Restricted benefit**
  Endometriosis
  
  **Clinical criteria:**
  The condition must be visually proven, AND
  The treatment must be for the short-term (up to 6 months).

  **Note**
  Only 1 course of not more than 6 months’ therapy will be authorised.

  **Restricted benefit**
  Breast cancer
  
  **Clinical criteria:**
  The condition must be hormone receptor positive, AND
  The treatment must be an alternative to adjuvant chemotherapy.

  **goserelin 3.6 mg implant, 1**

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- **GOSERELIN (&) BICALUTAMIDE**

  **Restricted benefit**
  Carcinoma of the prostate
  
  **Clinical criteria:**
  The condition must be metastatic (stage D), AND
  Patient must require a combination of an antiandrogen and a GnRH (LH-RH) agonist.

  **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.

  **goserelin 10.8 mg implant [1 implant] (&) bicalutamide 50 mg tablet [28 tablets], 1 pack**

<table>
<thead>
<tr>
<th>Max.Qty</th>
<th>Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<td>1248.63</td>
<td>37.70</td>
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  **goserelin 10.8 mg implant [1 implant] (&) bicalutamide 50 mg tablet [84 tablets], 1 pack**

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  **goserelin 3.6 mg implant [1 implant] (&) bicalutamide 50 mg tablet [28 tablets], 1 pack**

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LEUPRORELIN

Authority required (STREAMLINED)

Central precocious puberty

Treatment Phase: Continuing treatment

Clinical criteria:
Patient must have previously been issued with an authority prescription for this drug for this condition.

Treatment criteria:
Must be treated by a medical practitioner in consultation with a paediatric endocrinologist; OR
Must be treated by a medical practitioner in consultation with an endocrinologist specialising in paediatrics.

leuprorelin acetate 30 mg injection: modified release [1 syringe] (&) inert substance diluent [1 syringe], 1 pack

10255R

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<td>Lucrin Depot Paediatric 30 mg PDS [VE]</td>
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</table>

LEUPRORELIN

Authority required

Central precocious puberty

Treatment Phase: Initial treatment

Population criteria:
Patient must be under 8 years of age (girls) or 9 years of age (boys); OR
Patient must have received treatment with a gonadotropin releasing hormone analogue (GnRHa) for this condition prior to 1 May 2015.

Treatment criteria:
Must be treated by a paediatric endocrinologist; OR
Must be treated by an endocrinologist specialising in paediatrics.

leuprorelin acetate 30 mg injection: modified release [1 syringe] (&) inert substance diluent [1 syringe], 1 pack

10256T

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<td>Lucrin Depot Paediatric 30 mg PDS [VE]</td>
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LEUPRORELIN

Authority required (STREAMLINED)

Locally advanced (equivalent to stage C) or metastatic (equivalent to stage D) carcinoma of the prostate

leuprorelin acetate 22.5 mg injection: modified release [1 syringe] (&) inert substance diluent [1 syringe], 1 pack

8708H

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<tr>
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<td>Eligard 3 month [TL]</td>
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leuprorelin acetate 22.5 mg injection: modified release [1 x 22.5 mg syringe] (&) inert substance diluent [1 x 2 mL syringe], 1 pack

8876E

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leuprorelin acetate 30 mg injection: modified release [1 syringe] (&) inert substance diluent [1 syringe], 1 pack

8709J

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<td>Eligard 4 month [TL]</td>
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leuprorelin acetate 30 mg injection: modified release [1 x 30 mg syringe] (&) inert substance diluent [1 x 2 mL syringe], 1 pack

8877F

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leuprorelin acetate 45 mg injection: modified release [1 syringe] (&) inert substance diluent [1 syringe], 1 pack

8859G

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leuprorelin acetate 7.5 mg injection: modified release [1 syringe] (&) inert substance diluent [1 syringe], 1 pack

8707G

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leuprorelin acetate 7.5 mg injection: modified release [1 x 7.5 mg syringe] (&) inert substance diluent [1 x 2 mL syringe], 1 pack

<table>
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**TRIPTORELIN**

**Authority required (STREAMLINED) 3229**

Locally advanced (equivalent to stage C) or metastatic (equivalent to stage D) carcinoma of the prostate

**Triptorelin 11.25 mg injection [1 x 11.25 mg vial] (&) inert substance diluent [1 x 2 mL ampoule], 1 pack**

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**Triptorelin 22.5 mg injection [1 x 22.5 mg vial] (&) inert substance diluent [1 x 2 mL ampoule], 1 pack**

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</table>

**Triptorelin 3.75 mg injection [1 x 3.75 mg vial] (&) inert substance diluent [1 x 2 mL ampoule], 1 pack**

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**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.

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.

**Tamoxifen 10 mg tablet, 60**

<table>
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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.

For item codes 2110C and 1880Y, pharmaceutical benefits that have the form tablet 20 mg (base) are equivalent for the purposes of substitution.

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.

**Tamoxifen 20 mg tablet, 30**

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<th>Item No.</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
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**Tamoxifen 20 mg tablet, 60**

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* Genox 20 [AF]
* Tamosin [QA]
* Tamoxifen Sandoz [SZ]

* GenRx Tamoxifen [GX]
* Tamoxen 20 mg [GN]
### TOREMIFENE

toremifene 60 mg tablet, 30

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### BICALUTAMIDE

**Authority required (STREAMLINED)**

3674

Metastatic (equivalent to stage D) prostatic carcinoma in combination with GnRH (LH-RH) analogue therapy

**Note**

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

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.

bicalutamide 50 mg tablet, 28

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<td>Bicalutamide-GA [GN]</td>
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<td>Cosamide [AF]</td>
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</table>

### CYPROTERONE

**Authority required (STREAMLINED)**

1014

Advanced carcinoma of the prostate

**Authority required (STREAMLINED)**

1404

To reduce drive in sexual deviations in males

cyproterone acetate 100 mg tablet, 50

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<td>GenRx Cyproterone Acetate [GX]</td>
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</table>

### ENZALUTAMIDE

**Authority required**

Castration resistant metastatic carcinoma of the prostate

**Clinical criteria:**

- The treatment must not be used in combination with chemotherapy. AND
- Patient must have failed treatment with docetaxel due to resistance or intolerance; OR
- Patient must be unsuitable for docetaxel treatment on the basis of predicted intolerance to docetaxel, AND
- Patient must have a WHO performance status of 2 or less, AND
- Patient must not receive PBS-subsidised treatment with this drug if progressive disease develops while on this drug, AND
- Patient must not have received prior treatment with abiraterone, OR
- Patient must have developed intolerance to abiraterone of a severity necessitating permanent treatment withdrawal.

**Note**

Special Pricing Arrangements apply.

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

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

**Authority required (STREAMLINED) 3674**

Metastatic (equivalent to stage D) prostatic carcinoma in combination with GnRH (LH-RH) analogue therapy

**Note**

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

Shared Care Model:

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

### NILUTAMIDE

**Authority required (STREAMLINED) 3675**

Locally advanced (equivalent to stage C) or metastatic (equivalent to stage D) prostatic carcinoma, in combination with GnRH (LH-RH) analogue therapy

**Authority required (STREAMLINED) 3300**

Locally advanced (equivalent to stage C) or metastatic (equivalent to stage D) prostatic carcinoma, in conjunction with surgical orchidectomy

**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.

### ANASTROZOLE

**Restricted benefit**

Breast cancer

**Clinical criteria:**

The condition must be hormone receptor positive.

**Population criteria:**

Patient must not be pre-menopausal.

**Note**

This drug is not PBS-subsidised for primary prevention of breast cancer.

This drug is not PBS-subsidised for adjuvant hormonal treatment of early breast cancer where the total duration of this drug (or any other aromatase inhibitor) treatment extends beyond 5 years.

Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.
**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 not be pre-menopausal.

**exemestane 25 mg tablet, 30**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No of Rpts</th>
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<td>Exemestane Sandoz [SZ]</td>
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</table>

**EXEMESTANE**

**Restricted benefit**

Advanced breast cancer

**Clinical criteria:**
The condition must be hormone receptor positive, **AND**
The condition must have progressed following treatment with tamoxifen.

**Population criteria:**
Patient must not be pre-menopausal.

**Restricted benefit**

Early breast cancer

**Clinical criteria:**
The condition must be hormone receptor positive, **AND**
The condition must have previously been treated with tamoxifen for a minimum of 2 years.

**Population criteria:**
Patient must not be pre-menopausal.

**Note**

This drug is not PBS-subsidised for primary prevention of breast cancer.
This drug is not PBS-subsidised for adjuvant hormonal treatment of early breast cancer 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.

**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.

**exemestane 25 mg tablet, 30**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
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<td>Exemestane Sandoz [SZ]</td>
</tr>
</tbody>
</table>

**LETRCOZOLE**

**Restricted benefit**

Breast cancer

**Clinical criteria:**
The condition must be hormone receptor positive.

**Population criteria:**
Patient must not be pre-menopausal.

**Restricted benefit**

Early breast cancer

**Clinical criteria:**
The condition must be hormone receptor positive, **AND**
The treatment must be for extended adjuvant treatment of the condition commencing within 6 months of ceasing treatment with tamoxifen.
Population criteria:
Patient must not be pre-menopausal.

Note
This drug is not PBS-subsidised for primary prevention of breast cancer.
This drug is not PBS-subsidised for adjuvant hormonal treatment of early breast cancer where the total duration of this drug (or any other aromatase inhibitor) treatment extends beyond 5 years.

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

letrozole 2.5 mg tablet, 30

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Brand Name and Manufacturer

- APO-Letrozole [TX]
- Femara 2.5 mg [NV]
- Fera [QA]
- Letrozole Actavis [VN]
- Letrozole-DRLA [RZ]
- Letrozole-GA [GN]
- Letrozole RBX [RA]
- Lezole [UA]
- Pharmacy Choice Letrozole [RI]
- Chemmart Letrozole [CH]
- Femolet [AF]
- Gynotril [ER]
- Letrozole AN [EA]
- Letrozole FBM [FO]
- Letrozole generichealth [GQ]
- Letrozole Sandoz [SZ]
- Pharmacor Letrozole 2.5 [CR]
- Terry White Chemists Letrozole [TW]

Other hormone antagonists and related agents

- ABIRATERONE

Authority required

Castration resistant metastatic carcinoma of the prostate

Clinical criteria:
The treatment must be in combination with prednisone or prednisolone, AND
The treatment must not be used in combination with chemotherapy, AND
Patient must have failed treatment with docetaxel due to resistance or intolerance; OR
Patient must be unsuitable for docetaxel treatment on the basis of predicted intolerance to docetaxel, AND
Patient must have a WHO performance status of 2 or less, AND
Patient must not receive PBS-subsidised abiraterone if progressive disease develops while on abiraterone, AND
Patient must not have received prior treatment with enzalutamide; OR
Patient must have developed intolerance to enzalutamide of a severity necessitating permanent treatment withdrawal.

Note
Special Pricing Arrangements apply.

abiraterone acetate 250 mg tablet, 120

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Brand Name and Manufacturer

- Zytiga [JC]

-‡

DEGARELIX

Authority required (STREAMLINED)

Locally advanced (equivalent to stage C) or metastatic (equivalent to stage D) carcinoma of the prostate

degarelix 80 mg injection [1 x 80 mg vial] (&) inert substance diluent [1 syringe], 1 pack

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Brand Name and Manufacturer

- Firmagon 80mg [FP]

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.

degarelix 120 mg injection [2 x 120 mg vials] (&) inert substance diluent [2 syringes], 1 pack

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Brand Name and Manufacturer

- Firmagon 120mg [FP]
IMMUNOSTIMULANTS

Interferons

**INTERFERON ALFA-2A**

**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.

**Authority required**

Myeloproliferative disease with excessive thrombocytosis

**interferon alfa-2a 4.5 million international units/0.5 mL injection, 1 x 0.5 mL syringe**

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<thead>
<tr>
<th>Max.Qty Packs</th>
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**interferon alfa-2a 6 million international units/0.5 mL injection, 1 x 0.5 mL syringe**

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**interferon alfa-2a 9 million international units/0.5 mL injection, 1 x 0.5 mL syringe**

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**INTERFERON ALFA-2A**

**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.

**Authority required**

Low grade non-Hodgkin's lymphoma with clinical features suggestive of a poor prognosis, in combination with anthracycline-based chemotherapy

**interferon alfa-2a 3 million international units/0.5 mL injection, 1 x 0.5 mL syringe**

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**interferon alfa-2a 4.5 million international units/0.5 mL injection, 1 x 0.5 mL syringe**

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**interferon alfa-2a 6 million international units/0.5 mL injection, 1 x 0.5 mL syringe**

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**interferon alfa-2a 9 million international units/0.5 mL injection, 1 x 0.5 mL syringe**

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**INTERFERON ALFA-2A**

**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.

**Authority required**

Hairy cell leukaemia

**Authority required**

Myeloproliferative disease with excessive thrombocytosis

**interferon alfa-2a 3 million international units/0.5 mL injection, 1 x 0.5 mL syringe**

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**INTERFERON ALFA-2B**

**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.

**Authority required**
Hairy cell leukaemia

**INTERFERON ALFA-2B**

**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.

**Authority required**
Maintenance treatment of multiple myeloma once remission has been achieved with chemotherapy

**Authority required**
Low grade non-Hodgkin's lymphoma with clinical features suggestive of a poor prognosis, in combination with anthracycline-based chemotherapy

---

**INTERFERON BETA-1A**

**Authority required (STREAMLINED)**

**4881**
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, with written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient, AND
Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to the multiple sclerosis, in the preceding 2 years, AND
Patient must be ambulatory (without assistance or support).
Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records.

**Authority required (STREAMLINED)**

**4887**
Multiple sclerosis
Treatment Phase: Continuing treatment

**Clinical criteria:**
The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis, 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, AND
Patient must have demonstrated compliance with, and an ability to tolerate this therapy.

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

---

**INTERFERON BETA-1a Injection 44 micrograms (12,000,000 i.u.) in 0.5 mL single dose autoinjector, 12**

**4868B**
Max. Qnty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer
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1 5 .. 1057.11 37.70 Rebit 44 [SG]

**INTERFERON BETA-1a 30 microgram (6 million international units) injection [4 x 30 microgram vials] (&) inert substance diluent [4 x 1.1 mL syringes], 1 pack**

**8289G**
Max. Qnty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer
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1 5 .. 1057.11 37.70 Avonex [BD]

**INTERFERON BETA-1a 30 microgram/0.5 mL (6 million international units) injection, 4 x 0.5 mL syringes**

**8805K**
Max. Qnty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer
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1 5 .. 1057.11 37.70 Avonex [BD]
### Interferon beta-1a 44 microgram/0.5 mL (12 million international units) injection, 12 x 0.5 mL syringes

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### Interferon beta-1a 44 microgram/0.5 mL (12 million international units) injection, 4 x 1.5 mL cartridges

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## Interferon beta-1b

**Authority required (STREAMLINED)**

### 4881

#### 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, with written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient, AND
- Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to the multiple sclerosis, in the preceding 2 years, AND
- Patient must be ambulatory (without assistance or support).
- Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient’s medical records.

**Note**

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

### 4887

#### Multiple sclerosis

**Treatment Phase:** Continuing treatment

**Clinical criteria:**
- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis, 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, AND
- Patient must have demonstrated compliance with, and an ability to tolerate this therapy.

**Note**

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

### Peginterferon beta-1a

**Authority required (STREAMLINED)**

### 4881

#### 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, with written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient, AND
- Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to the multiple sclerosis, in the preceding 2 years, AND
- Patient must be ambulatory (without assistance or support).
- Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient’s medical records.

**Note**

- No increase in the maximum quantity or number of units may be authorised.
- No increase in the maximum number of repeats may be authorised.
PEGINTERFERON BETA-1A

**Authority required (STREAMLINED)**

4887
Multiple sclerosis
Treatment Phase: Continuing treatment

**Clinical criteria:**
The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis, **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, **AND**
Patient must have demonstrated compliance with, and an ability to tolerate this therapy.

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

BACILLUS CALMETTE AND GUERIN-CONNAUGHT STRAIN

**Restricted benefit**
Treatment of carcinoma in situ of the urinary bladder

Bacillus Calmette and Guerin-Connaught strain 660 million colony forming units injection [1 x 81 mg vial] (**&**) inert substance diluent [1 x 3 mL vial], 1 pack

1140B

**GLATIRAMER ACETATE**

**Authority required (STREAMLINED)**

4881
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, with written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient, **AND**
Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to the multiple sclerosis, in the preceding 2 years, **AND**
Patient must be ambulatory (without assistance or support).
Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records.

**Authority required (STREAMLINED)**

4887
Multiple sclerosis
Treatment Phase: Continuing treatment

**Clinical criteria:**
The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis, **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, **AND**
Patient must have demonstrated compliance with, and an ability to tolerate this therapy.
Note
No increase in the maximum quantity or number of units may be authorised.
No increase in the maximum number of repeats may be authorised.

Glatiramer acetate 20 mg/mL injection, 28 x 1 mL syringes

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**IMMUNOSUPPRESSANTS**

**Selective immunosuppressants**

**ABATACEPT**

**Authority required**

Severe active rheumatoid arthritis
Treatment Phase: Continuing treatment.

**Clinical criteria:**

Patient must have a documented history of severe active rheumatoid arthritis, AND
Patient must have demonstrated an adequate response to treatment with this drug, AND
Patient must have received this drug as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment, AND
Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction, AND

The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

**Population criteria:**

Patient must be aged 18 years or older.

**Treatment criteria:**

Must be treated by a rheumatologist; OR
Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab or tocilizumab.

An adequate response to treatment is defined as:

- an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;
- AND either of the following:
  (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
  (b) a reduction in the number of the following active joints, from at least 4, by at least 50%:
    (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
    (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

1. a completed authority prescription form; and
2. a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

All applications for continuing treatment with this drug must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**Note**

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

Special Pricing Arrangements apply.

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Prior Written Approval of Complex Drugs
TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alpha antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab) and the T-cell co-stimulation modulator (abatacept).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alpha antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:
- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy;
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alpha antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab and tocilizumab, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:
- Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient’s weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:
- A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Rituximab patients:
A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.
Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.
A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept patients:
Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.
In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements. To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

**Authority required**

Severe active rheumatoid arthritis
Treatment Phase: Continuing Treatment – balance of supply.

**Clinical criteria:**
Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, AND
The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Treatment criteria:**
Must be treated by a rheumatologist; OR
Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Note**
Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826


**ABATACEPT**

**Authority required**

Severe active rheumatoid arthritis

**Clinical criteria:**

- Patient must have severe active rheumatoid arthritis, AND
- Patient must have received no PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition in the previous 24 months, AND
- Patient must not have failed previous PBS-subsidised treatment with this drug for this condition, and have not already failed, or ceased to respond to, PBS-subsidised bDMARD treatment for this condition 5 times, AND
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above, must include at least 3 months continuous treatment with each of at least 2 DMARDs, with one or more of the following DMARDs being used in place of the DMARDs which are contraindicated or not tolerated: (i) azathioprine at a dose of at least 1 mg/kg per day; and/or (ii) cyclosporin at a dose of at least 2 mg/kg/day; and/or (iii) sodium aurothiomalate at a dose of 50 mg weekly, AND
- Patient must not receive more than 16 weeks of treatment under this restriction, AND

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab or tocilizumab.

If methotrexate is contraindicated according to the TGA-approved Product Information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable. The application must include details of the DMARDs trialed, their doses and duration of treatment, and all relevant contraindications and/or intolerances.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance and dose for each DMARD must be provided in the authority application.

The authority application must be made in writing and must include:

1. completed authority prescription forms; and
2. a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form; and
3. a signed patient acknowledgement.

**Initial treatment with an I.V. loading dose:** Two completed authority prescriptions must be submitted with the initial application. One prescription must be for the I.V. loading dose for sufficient vials for one dose based on the patient’s weight with no repeats. The second prescription must be written for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats.

**Initial treatment 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.

Assessment of a patient’s response to an initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted no later than 1 month from the date of completion of this initial course of treatment.
Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

Applications for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient’s most recent course of PBS-subsidised treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

- an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either
  - (a) a total active joint count of at least 20 active (swollen and tender) joints; or
  - (b) at least 4 active joints from the following list of major joints:
    (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
    (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Where the baseline joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP is provided with the initial application, the same marker will be used to determine response.

Note

The Department of Human Services website (www.humanservices.gov.au) has details of the toxicities, including severity, which will be accepted for the following purposes:

(a) exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose;

(b) substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial;

(c) exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy.

TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alpha antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab) and the T-cell co-stimulation modulator (abatacept).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any one time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alpha antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:

- A patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy.
- A patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alpha antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (initial 1); or

(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than
24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab and tocilizumab, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:

Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient’s weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:

A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD when having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept patients:

Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD.

Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD.
However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements. To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

**Authority required**

**Severe active rheumatoid arthritis**

**Treatment Phase: Initial treatment - Initial 2 (change or re-commencement of treatment after break of less than 24 months).**

**Clinical criteria:**

- Patient must have a documented history of severe active rheumatoid arthritis, AND
- Patient must have received prior PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition and are eligible to receive further bDMARD therapy, AND
- Patient must not receive more than 16 weeks of treatment under this restriction, AND
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab or tocilizumab.

The authority application must be made in writing and must include:

(a) completed authority prescription forms; and
(b) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

Applications for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient’s most recent course of PBS-subsidised treatment, within the timeframes specified below.

Initial treatment with an I.V. loading dose: Two completed authority prescriptions must be submitted with the initial application. One prescription must be for the I.V. loading dose for sufficient vials for one dose based on the patient’s weight with no repeats. The second prescription must be written for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats.

Initial treatment with no loading dose: One completed authority prescription must be submitted with the initial application. The prescription must be written with a maximum quantity of 4 and up to 3 repeats.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to a treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD.

An adequate response to treatment is defined as:

- an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND
- either of the following:
  (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
  (b) a reduction in the number of the following active joints, from at least 4, by at least 50%:
    (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
    (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

**Note**

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

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

HOBART TAS 7001
TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab) and the T-cell co-stimulation modulator (abatacept).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:
- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to the therapy;
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with a PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010:

(a) Initial treatment.

Applications for initial treatment should be made where:
(i) a patient has received prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab and tocilizumab, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:

Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients, two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient’s weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:

A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New
baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction. Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled. Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept patients:

Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation. In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alpha antagonist treatment. To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

the Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements. To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months) or Initial 2 (change or recommencement of treatment after break of less than 24 months) – balance of supply.

**Clinical criteria:**

Patient must have received insufficient therapy with this drug under the Initial 1 (new patient or patient recommencing treatment after break of more than 24 months) restriction to complete 16 weeks treatment; OR

Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement of treatment after break of less than 24 months) restriction to complete 16 weeks treatment. **AND**

The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Treatment criteria:**
Must be treated by a rheumatologist; OR
Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Note**

Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826

HOBART TAS 7001

**abatacept 125 mg/mL injection, 4 x 1 mL syringes**

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**EVEROLIMUS**

**Caution**

Careful monitoring of patients is mandatory.

**Authority required**

Maintenance therapy, following initiation and stabilisation of treatment with everolimus and where therapy remains under the supervision and direction of the transplant unit reviewing that patient, of patients with renal transplants. The name of the specialised transplant unit reviewing treatment and the date of the latest review at the specialised transplant unit must be included in the authority application.

**Authority required**

Maintenance therapy, following initiation and stabilisation of treatment with everolimus and where therapy remains under the supervision and direction of the transplant unit reviewing that patient, of patients with cardiac transplants. The name of the specialised transplant unit reviewing treatment and the date of the latest review at the specialised transplant unit must be included in the authority application.

**everolimus 1 mg tablet, 60**

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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.
fingolimod 500 microgram capsule, 28

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LEFLUNOMIDE

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.

Authority required (STREAMLINED)

2682
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.

leflunomide 10 mg tablet, 30

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LEFLUNOMIDE

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.

Authority required (STREAMLINED)

2644
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.

leflunomide 10 mg tablet, 30

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Mycophenolate

Caution
Careful monitoring of patients is mandatory.

mycophenolate 180 mg tablet: enteric, 120 tablets

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mycophenolate 360 mg tablet: enteric, 120 tablets

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mycophenolate mofetil 1 g/5 mL oral liquid: powder for, 165 mL

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mycophenolate mofetil 500 mg tablet, 50

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### MYCOPHENOLATE

**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.

**Mycophenolate Capsule 250 mg, 50**

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**Mycophenolate mofetil 250 mg capsule, 100**

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### SIROLIMUS

**Caution**

Careful monitoring of patients is mandatory.

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**sirolimus 1 mg/mL oral liquid, 60 mL**

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### TERIFLUNOMIDE

**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.

**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.

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

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**Tumor necrosis factor alpha (TNF-)** inhibitors

### 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 to determine response.
The authority application must be made in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.
All applications for continuing treatment with adalimumab must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with adalimumab, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.
Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with adalimumab.
If a patient fails to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle.

**Note**
Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
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 repeatedly with respect to the indices of disease severity (joint count and ESR/CRP) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.
(3) Baseline measurements to determine response. The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.

(4) Re-commencement of treatment after a 24 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 24 months, must requalify for treatment under the Initial 1 treatment restriction.

**Authority required**
- Severe active juvenile idiopathic arthritis
- Treatment Phase: Continuing treatment – balance of supply

**Clinical criteria:**
- Patient must have received insufficient adalimumab therapy under the Continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**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

### adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges

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### adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes

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### ADALIMUMAB

**Authority required**
- Initial 1
- Initial treatment of complex refractory FISTULISING CROHN DISEASE.

Initial PBS-subsidised treatment with adalimumab by a gastroenterologist or a consultant physician as specified in the NOTE below, of a patient with complex refractory fistulising Crohn disease who:
- (a) has confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician as specified in the NOTE below; and
- (b) has an externally draining enterocutaneous or rectovaginal fistula; and
- (c) has signed a patient acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criteria for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment.

**NOTE:** Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

Authority applications must be made in writing and must include:
- (a) two completed authority prescription forms; and
- (b) a completed Fistulising Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
  - (i) a completed current Fistula Assessment Form including the date of assessment of the patient’s condition; and
  - (ii) a signed patient acknowledgement.

The most recent fistula assessment must be no more than 1 month old at the time of application.

A maximum of 16 weeks treatment will be authorised under this criterion.

Two completed authority prescriptions must be submitted with every initial application for adalimumab. One prescription must be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats. The second prescription must be written for 2 doses of 40 mg and 2 repeats. Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with adalimumab may be...
requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

An assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of therapy so that there is adequate time for a response to be demonstrated.

This assessment must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with adalimumab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised adalimumab treatment

**Authority required**

Initial 2

Change or re-commencement of treatment of complex refractory FISTULISING CROHN DISEASE.

Initial PBS-subsidised treatment with adalimumab of complex refractory fistulising Crohn disease by a gastroenterologist or a consultant physician as specified in the NOTE below, of a patient with complex refractory fistulising Crohn disease who:

(a) has a documented history of complex refractory fistulising Crohn disease; and

(b) in this treatment cycle, has received prior PBS-subsidised treatment with adalimumab or infliximab for a draining enterocutaneous or rectovaginal fistula; and

(c) has not failed PBS-subsidised therapy with adalimumab for this condition more than once in the current treatment cycle.

**NOTE:** Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of TNF-alfa antagonist therapy within the time frames specified in the relevant restriction.

Where the most recent course of PBS-subsidised TNF-alfa antagonist treatment was approved under an initial treatment restriction, the patient must have been assessed for response to that course following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

If the response assessment to the previous course of TNF-alfa antagonist treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of TNF-alfa antagonist.

Authority applications must be made in writing and must include:

(a) two completed authority prescription forms; and

(b) a completed Fistulae 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

**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-alpha 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-alpha antagonist without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a TNF-alpha antagonist while they continue to show a response to therapy. A patient who received PBS-subsidised TNF-alpha antagonist treatment prior to 1 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-alpha antagonist more than twice. Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised TNF-alpha antagonist therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised TNF-alpha antagonist treatment in the most recent cycle to the date of the first application for initial treatment with a TNF-alpha antagonist under the new treatment cycle. A patient who has failed fewer than 3 trials of TNF-alpha antagonists in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle. A patient who has failed fewer than 3 trials of TNF-alpha antagonists in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle. There is no limit to the number of treatment cycles a patient may undertake in their lifetime. (1) How to prescribe PBS-subsidised TNF-alpha antagonist therapy after 1 April 2011. (a) Initial treatment. Applications for initial treatment should be made where: (i) a patient has received no prior PBS-subsidised TNF-alpha antagonist treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or (ii) a patient has received prior PBS-subsidised (initial or continuing) TNF-alpha antagonist therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or (iii) a patient wishes to re-commence treatment with a specific TNF-alpha antagonist following a break in PBS-subsidised therapy with that agent (Initial 2). Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks of therapy for 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-alpha antagonist. For second and subsequent courses of PBS-subsidised TNF-alpha 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-alpha 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-alpha 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-alpha 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-alpha antagonist. (2) Swapping therapy. Once initial treatment with the first PBS-subsidised TNF-alpha antagonist is approved, a patient may swap if eligible to the alternate TNF-alpha antagonist within the same treatment cycle. A patient may trial the alternate TNF-alpha antagonist at any time, regardless of whether they are receiving therapy (initial or continuing) with a TNF-alpha antagonist at the time of the application. However, they cannot swap to a particular TNF-alpha 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-alpha antagonist should be accompanied by the approved authority prescription or remaining repeats for the TNF-alpha 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-alpha 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-alpha 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...
adoximubab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes
8963R Max Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer
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8961P Max Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer
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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 predetemined 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 82)] 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 continuation of treatment for those patients who meet the continuation criteria.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with adalimumab.

A maximum of 24 weeks treatment will be approved under this criterion.

Where fewer than 5 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Patients may qualify for PBS-subsidised treatment under this restriction once only

**Authority required**

Continuing treatment of complex refractory FISTULISING CROHN DISEASE.

Continuing PBS-subsidised treatment with adalimumab by a gastroenterologist, a consultant physician as specified in the NOTE below or other consultant physician in consultation with a gastroenterologist, of a patient who:

(a) has a documented history of complex refractory fistulising Crohn disease; and

(b) has demonstrated or sustained an adequate response to treatment with adalimumab.

**NOTE:** Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

An adequate response is defined as:

(a) a decrease from baseline in the number of open draining fistulae of greater than or equal to 50%; and/or

(b) a marked reduction in drainage of all fistula(e) from baseline, together with less pain and induration as reported by the patient.

Authority applications must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Fistulising Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes a completed Fistula Assessment form including the date of the assessment of the patient’s condition.

The fistula assessment must be no more than 1 month old at the time of application.

If the application is the first application for continuing treatment with adalimumab, an assessment of the patient’s response must be made following a minimum of 12 weeks after the first dose so that there is adequate time for a response to be demonstrated.

An assessment of the patient’s response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criteria.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with adalimumab.

Patients are eligible to receive continuing adalimumab treatment in courses of up to 24 weeks providing they continue to sustain the response.

A maximum of 24 weeks treatment will be authorised under this criterion.

Where fewer than 5 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday)

**Note**

Any queries concerning the arrangements to prescribe adalimumab may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe adalimumab should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826

HOBART TAS 7001

**TREATMENT OF COMPLEX REFRACTORY FISTULISING CROHN DISEASE**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab and infliximab for patients with complex refractory fistulising Crohn disease. Where the term ‘tumour necrosis factor (TNF) alfa antagonist’ appears in the following NOTES and restrictions, it refers to adalimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 2 TNF-alfa antagonists at any 1 time.

From 1 April 2011, under the PBS, all patients will be able to commence a treatment cycle where they may trial each PBS-subsidised TNF-alfa antagonist without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a TNF-alfa antagonist while they continue to show a response to therapy.

A patient who received PBS-subsidised TNF-alfa antagonist treatment prior to 1 April 2011 is considered to be in their first cycle as of 1 April 2011.

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.

(a) 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.

(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.

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

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges

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adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes

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**General**

- **ADALIMUMAB**
  
  **Authority required**
  Severe active rheumatoid arthritis
  Treatment Phase: Continuing treatment

  **Clinical criteria:**
  Patient must have a documented history of severe active rheumatoid arthritis, AND
  Patient must have demonstrated an adequate response to treatment with this drug, AND
  Patient must have received this drug as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment, AND
  Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction, AND
  The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

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

  **Treatment criteria:**
  Must be treated by a rheumatologist; OR
  Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

  For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab or tocilizumab.

  An adequate response to treatment is defined as:
  an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;
  AND either of the following:
  (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
  (b) a reduction in the number of the following active joints, from at least 4, by at least 50%:
     (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
     (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

  Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

  The authority application must be made in writing and must include:
  (1) a completed authority prescription form; and
  (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

  All applications for continuing treatment with this drug must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

  Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

  If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

  **Note**
  No increase in the maximum quantity or number of units may be authorised.
  No increase in the maximum number of repeats may be authorised.
  Applications for treatment with this drug where the dosing frequency exceeds 40 mg per fortnight will not be approved.

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

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

  Applications for authority to prescribe should be forwarded to:
  Department of Human Services
  Prior Written Approval of Complex Drugs
  Reply Paid 9826

  **HOBART TAS 7001**

  **TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS**

  The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alpha antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab) and the T-cell co-stimulation modulator (abatacept).

  Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.
In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:

- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has less 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 authorisation is limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab and tocilizumab, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:

Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient’s weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:

A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive the course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate,
where it applies, must be met for each bDMARD trialled. Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept patients:

Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

the Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment authority application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Continuing Treatment – balance of supply.

**Clinical criteria:**

Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, **AND**

The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Treatment criteria:**

Must be treated by a rheumatologist; **OR**

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Note**

Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

HOBART TAS 7001

### adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges

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### adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes

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**ADALIMUMAB**

**Authority required**

**Continuing treatment (Whole body)**

Continuing PBS-subsidised treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over:

(a) who have a documented history of severe chronic plaque psoriasis; and

(b) whose most recent course of PBS-subsidised biological treatment for this condition in this Treatment Cycle was with adalimumab; and

(c) who have demonstrated an adequate response to their most recent course of treatment with adalimumab.

An adequate response to treatment is defined as:

- A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the pre-biological treatment baseline value for this Treatment Cycle.
- This assessment must be provided to Medicare Australia no later than 4 weeks from the cessation of that treatment course.
- If the application is the first application for continuing treatment with adalimumab, the assessment of response must be after a minimum of 12 weeks of treatment with an initial course.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare 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 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 course of treatment 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 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.

A maximum of 24 weeks of treatment with adalimumab will be authorised under this restriction.
Where fewer than 5 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for continuing authority applications, or for treatment that would otherwise extend the treatment period beyond 24 weeks. A PASI assessment of the patient's response must be conducted within 4 weeks prior to completion of this course of treatment. This assessment, which will be used to determine eligibility for further continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with adalimumab. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss. It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised adalimumab treatment. The PASI assessment for continuing treatment must be performed on the same affected area assessed at baseline. Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may re-commence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

Note

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

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. The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline. 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.

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

Special Pricing Arrangements apply.

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges

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adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes

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- **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**
ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

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 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.

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
(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.
Applications for a patient who has received PBS-subsidised treatment with adalimumab in this treatment cycle and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised adalimumab treatment, within the timeframes specified below.
Where the most recent course of PBS-subsidised adalimumab treatment was approved under either of the Initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.
Where the most recent course of PBS-subsidised adalimumab treatment was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.
Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with adalimumab.
If a patient fails to respond to PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle.
An adequate response to treatment is defined as:
an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;
AND either of the following:
(a) an active joint count of fewer than 10 active (swollen and tender) joints; or
(b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or
(c) a reduction in the number of the following active joints, from at least 4, by at least 50%:
(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

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

HOBART TAS 7001
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 and 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.

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
ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months) or Initial 2 (change or recommencement of treatment after break of less than 24 months) – balance of supply

Clinical criteria:
Patient must have received insufficient adalimumab therapy under the Initial 1 (new patient or patient recommencing treatment after break of more than 24 months) restriction to complete 16 weeks treatment; OR
Patient must have received insufficient adalimumab therapy under the Initial 2 (change or recommencement of treatment after break of less than 24 months) restriction to complete 16 weeks treatment, AND
The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Treatment criteria:
Must be treated by a rheumatologist; OR
Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Note
Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826

HOBART TAS 7001

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges

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adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes

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- ADALIMUMAB

Authority required
Ankylosing spondylitis
Treatment Phase: Continuing treatment

Clinical criteria:
Patient must have a documented history of active ankylosing spondylitis, AND
Patient must have received this drug as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment in this treatment cycle, AND
Patient must have demonstrated an adequate response to treatment with this drug.

Population criteria:
Patient must be an adult.

Treatment criteria:
Must be treated by a rheumatologist.
An adequate response is defined as an improvement from baseline of at least 2 of the BASDAI and 1 of the following:
(a) an ESR measurement no greater than 25 mm per hour; or
(b) a CRP measurement no greater than 10 mg per L; or
(c) an ESR or CRP measurement reduced by at least 20% from baseline.
Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and supplied in all subsequent continuing treatment applications.
The authority application must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form.
All measurements provided must be no more than 1 month old at the time of application.
A maximum of 24 weeks of treatment with this drug will be authorised under this criterion.
All applications for continuing treatment with this drug must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment following an initial treatment course it must be made following a minimum of 12 weeks of treatment with this drug. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.
Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised bDMARD was approved in this cycle and the date of the first application under a new cycle.

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

Authoritaty 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.

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

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

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges

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adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes

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■ ADALIMUMAB

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months)

Clinical criteria:

Patient must have severe active rheumatoid arthritis, AND

Patient must have received no PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition in the previous 24 months, AND

Patient must not have failed previous PBS-subsidised treatment with this drug for this condition, and have not already failed, or ceased to respond to, PBS-subsidised bDMARD treatment for this condition 5 times, AND

Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a
ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

doof of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR

Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR

Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above, must include at least 3 months continuous treatment with each of at least 2 DMARDs, with one or more of the following DMARDs being used in place of the DMARDs which are contraindicated or not tolerated: (i) azathioprine at a dose of at least 1 mg/kg per day; and/or (ii) cyclosporin at a dose of at least 2 mg/kg/day; and/or (iii) sodium aurothiomalate at a dose of 50 mg weekly. **AND**

Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

Patient must be aged 18 years or older.

**Treatment criteria:**

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab or tocilizumab.

If methotrexate is contraindicated according to the TGA-approved Product Information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance and dose for each DMARD must be provided in the authority application.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form; and

(3) a signed patient acknowledgement.

Applications for a patient who has received PBS-subsidised treatment with this drug and who wishes to re commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS subsidised treatment with this drug, within the timeframes specified below.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

- an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either
  - (a) a total active joint count of at least 20 active (swollen and tender) joints; or
  - (b) at least 4 active joints from the following list of major joints:
    - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
    - (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Where the baseline joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP is provided with the initial application, the same marker will be used to determine response.

**Note**

The Department of Human Services website (www.humanservices.gov.au) has details of the toxicities, including severity, which will be accepted for the following purposes:
Schedule of Pharmaceutical Benefits

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

(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.

Authority required
Severe active rheumatoid arthritis
Treatment Phase: Initial treatment - Initial 2 (change or re-commencement of treatment after break of less than 24 months)

Clinical criteria:
Patient must have a documented history of severe active rheumatoid arthritis, AND
Patient must have received prior PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition and are eligible to receive further bDMARD therapy, AND
Patient must not receive more than 16 weeks of treatment under this restriction.

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

Treatment criteria:
Must be treated by a rheumatologist; OR
Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.
For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab or tocilizumab.
The authority application must be made in writing and must include:
(a) a completed authority prescription form and
(b) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.
Application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.
Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.
Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.
If a patient fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.
Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.
If a patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD.
An adequate response to treatment is defined as:
an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;
AND either of the following:
(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:
   (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
   (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Note
No increase in the maximum quantity or number of units may be authorised.
No increase in the maximum number of repeats may be authorised.
Applications for treatment with this drug where the dosing frequency exceeds 40 mg per fortnight will not be approved.

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

HOBART TAS 7001
TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alpha antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab) and the T-cell co-stimulation modulator (abatacept).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alpha antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:
- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy.
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alpha antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the new application for treatment with a bDMARD.

1. How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.
   (a) Initial treatment.
   Applications for initial treatment should be made where:
   (i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
   (ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
   (iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or
   (iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

   Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

   Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab and tocilizumab, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

   A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

   Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks 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 (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

   Abatacept patients:
   - Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient’s weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

   Rituximab patients:
   - A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

   Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

   It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

   Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

   Rituximab patients:
   - A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept patients:

Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements. To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months) or Initial 2 (change or recommencement of treatment after break of less than 24 months) – balance of supply.

Clinical criteria:

Patient must have received insufficient therapy with this drug under the Initial 1 (new patient or patient recommencing treatment after break of more than 24 months) restriction to complete 16 weeks treatment; OR

Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement of treatment after break of less than 24 months) restriction to complete 16 weeks treatment, AND

The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Note

Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:

Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826

HOBART TAS 7001
## ADALIMUMAB

**Authority required**

Severe psoriatic arthritis

**Clinical criteria:**

Patient must have a documented history of severe active psoriatic arthritis, **AND**

Patient must have received this drug as their most recent course of PBS-subsidised treatment with a biological agent for this condition in the current Treatment Cycle, **AND**

Patient must demonstrate, at the time of application, an adequate response to treatment with this drug, **AND**

Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

**Population criteria:**

Patient must be an adult.

**Treatment criteria:**

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab or infliximab.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications.

All applications for continuing treatment with this drug must include a measurement of response to the most recent course of PBS-subsidised therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with the initial treatment course.

Where a response assessment is not submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

**Note**

Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

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

Prescribing information (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
Where the term ‘biological agents’ appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab and infliximab only.

Patients receiving PBS-subsidised treatment for psoriatic arthritis are able to commence a ‘Biological Treatment Cycle’ (Cycle), where they may trial biological agents without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

Following demonstration of response to initial treatment, these biological agents are available under the PBS for continuing treatment as set out in the continuing treatment restriction for each agent.

Once patients have either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological therapy before they are eligible to commence another Cycle [further details are under ‘(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy’ below].

The duration of the break in therapy will be measured from the date the last approval for PBS-subsidised treatment was granted in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Cycle.

Within the same Cycle, patients are not allowed to fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for any biological agent, they must change to an alternate agent which they have not previously failed, if they wish to continue PBS-subsidised biological treatment.

Patients for whom a break in PBS-subsidised therapy of less than 5 years has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle.

There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe active psoriatic arthritis.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); and

(ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; and

(iii) patients wish to re-commence therapy with a specific biological agent following a break in PBS-subsidised therapy with that specific agent (Initial 3).

Applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept and golimumab, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), and 22 weeks of therapy for infliximab. It is recommended that patients be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological agent supply.

Patients must be assessed for response to any course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

Grandfather patients - certolizumab pegol only.

For patients who commenced treatment with certolizumab pegol for psoriatic arthritis prior to 1 April 2015, applications for initial PBS-subsidised treatment as continuing therapy may be made under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with any biological agent prior to PBS listing of that agent.

Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment for all agents. Approval will be based on the criteria included in the relevant restriction.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological agent, patients may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. Patients are eligible to receive continuing biological treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

Patients must be assessed for response to a course of continuing therapy, and the assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

(3) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate biological agent without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements.

Patients may swap to an alternate biological agent at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological agent at the time of the application or not.

Within a Treatment Cycle patients may alternate between therapy with any biological agent of their choice (1 at a time) providing:

(i) they have not received PBS-subsidised treatment with that particular biological agent previously; or

(ii) they have demonstrated an adequate response to that particular biological agent if they have previously trialled it on the PBS; and

(iii) they have not previously failed to respond to treatment 3 times in this Treatment Cycle.

To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the biological agent the patient is ceasing.
(4) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the indices of disease severity submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment application is submitted within a treatment Cycle and these revised baseline measurements will be used to assess response.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.
(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

Patients who wish to trial a second or subsequent treatment Cycle following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment with respect to both the indices of disease severity. Patients must have received treatment with methotrexate and sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured.

**Authority required**
Severe psoriatic arthritis

**Treatment Phase:** Continuing treatment - balance of supply

**Clinical criteria:**
Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, **AND**
The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Treatment criteria:**
Must be treated by a rheumatologist; **OR**
Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

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

Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

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- **ADALIMUMAB**

  **Authority required**
  Initial 1 (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
(ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and
(iii) the signed patient acknowledgement.

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).

Detailed guidance on how PBS applications for adalimumab are processed is available on the Medicare Australia website (www.medicareaustralia.gov.au).
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 intravascular 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 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 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 treatment within the timeframes specified in the relevant restriction.

Where the most recent course of PBS-subsidised TNF-alfa antagonist treatment was approved under an initial treatment restriction, the patient must have been assessed for response to that course following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

If the response assessment to the previous course of TNF-alfa antagonist treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of TNF-alfa antagonist.

Authority applications must be made in writing and must include:

(a) two completed authority prescription forms; and
(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
   (i) reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criteria, if relevant; and
   (ii) details of prior TNF alfa antagonist treatment including details of date and duration of treatment.

A maximum of 16 weeks of treatment will be approved under this criterion.

Two completed authority prescriptions must be submitted with every initial application for adalimumab. One prescription must be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats. The second prescription must be written for 2 doses of 40 mg and 2 repeats. Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with adalimumab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

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

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(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 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

(c) 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.

Written applications for authority to prescribe adalimumab should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs
HOBART TAS 7001
TREATMENT OF ADULT PATIENTS WITH SEVERE REFRACTORY CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab and infliximab for adult patients with severe refractory Crohn disease. Where the term 'tumour necrosis factor (TNF) alpha antagonist' appears in the following NOTES and restrictions, it refers to adalimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 2 TNF-alpha antagonists at any 1 time.

From 1 August 2008, under the PBS, all patients will be able to commence a treatment cycle where they may trial each PBS-subsidised TNF-alpha antagonist without having to experience a disease flare when swapping to the alternate agent.

Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a TNF-alpha antagonist while they continue to show a response to therapy.

A patient who received PBS-subsidised TNF-alpha antagonist treatment prior to 1 August 2008 is considered to be in their first cycle as of 1 August 2008.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised TNF-alpha antagonist more than twice.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised TNF-alpha antagonist therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised TNF-alpha antagonist treatment in the most recent cycle to the date of the first application for initial treatment with a TNF-alpha antagonist under the new treatment cycle.

A patient who has failed fewer than 3 trials of TNF-alpha antagonists in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of TNF-alpha antagonists in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised TNF-alpha antagonist therapy after 1 August 2008.

(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised TNF-alpha antagonist treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
(ii) a patient has received prior PBS-subsidised (initial or continuing) TNF-alpha antagonist therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or
(iii) a patient wishes to re-commence treatment with a specific TNF-alpha antagonist following a break in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks of therapy for 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-alpha antagonist.

For second and subsequent courses of PBS-subsidised TNF-alpha 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-alpha 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-alpha 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-alpha 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-alpha antagonist.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised TNF-alpha antagonist is approved, a patient may swap if eligible to the alternate TNF-alpha 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-alpha antagonist at any time, regardless of whether they are receiving therapy (initial or continuing) with a TNF-alpha antagonist at the time of the application. However, they cannot swap to a particular TNF-alpha antagonist if they have failed to respond to prior treatment with that drug in 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-alpha antagonist should be accompanied by the approved authority prescription or remaining repeats for the TNF-alpha 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.

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

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges

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adalimumab 40 mg/0.8 mL injection, 6 x 0.8 mL cartridges

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## ADALIMUBAB

**Authority required**

Initial 3 (grandfather)

Initial PBS-subsidised treatment of Crohn disease in a patient assessed by CDAI who has previously received non-PBS-subsidised therapy with adalimumab.

Initial PBS-subsidised supply for continuing treatment with adalimumab by a gastroenterologist, a consultant physician as specified in the NOTE below, or other consultant physician in consultation with a gastroenterologist of a patient who:

(a) has a documented history of severe refractory Crohn disease and was receiving treatment with adalimumab prior to 9 November 2007; and

(b) had a Crohn Disease Activity Index (CDAI) Score of greater than or equal to 300 prior to commencing treatment with adalimumab. Where a baseline CDAI assessment is not available, please call Medicare Australia on 1800 700 270 to discuss; and

(c) has signed a patient acknowledgement indicating that they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and

(d) has demonstrated or sustained an adequate response to treatment with adalimumab. For advice please contact Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [general medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

An adequate response to adalimumab treatment is defined as a reduction in Crohn Disease Activity Index (CDAI) Score to no greater than 150.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and
An adequate response to adalimumab treatment is defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150.

Applications for authorisation must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) the completed 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 CDAI assessment must be no more than 1 month old at the time of application. If the application is the first application for continuing treatment with adalimumab, a CDAI assessment of the patient's condition 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.

The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with adalimumab.

A maximum of 24 weeks treatment will be approved under this criterion.

Where fewer than 5 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Patients may qualify for PBS-subsidised treatment under this restriction once only

**Authority required**

Continuing treatment of Crohn disease in a patient assessed by CDAI.

Continuing PBS-subsidised treatment with adalimumab by a gastroenterologist, a consultant physician as specified in the NOTE below or other consultant physician in consultation with a gastroenterologist, of a patient who:
(a) has a documented history of severe refractory Crohn disease; and
(b) has demonstrated or sustained an adequate response to treatment with adalimumab.

**NOTE:** Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

An adequate response to adalimumab treatment is defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150.

Applications for authorisation must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) the completed 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 CDAI assessment must be no more than 1 month old at the time of application. If the application is the first application for continuing treatment with adalimumab, a CDAI assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of therapy so that there is adequate time for a response to be demonstrated.

The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with adalimumab.

Patients are eligible to receive continuing adalimumab treatment in courses of up to 24 weeks providing they continue to sustain the response.

A maximum of 24 weeks treatment will be authorised under this criterion.

Where fewer than 5 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday)

**Authority required**

Continuing treatment of Crohn disease in a patient with short gut syndrome or an ostomy patient.

Continuing PBS-subsidised treatment with adalimumab by a gastroenterologist, a consultant physician as specified in the NOTE below or other consultant physician in consultation with a gastroenterologist, of a patient who:
(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:

- a reduction in Crohn Disease Activity Index (CDAI) Score to no greater than 150; or
- 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
- normalisation of lactoferrin or calprotectin level; AND/OR
- 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) 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 completed Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition; or
- the reports and dates of the pathology test or diagnostic imaging test(s) used to assess response to therapy; or
- the date of clinical assessment.

All assessments must be no more than 1 month old at the time of application.

If the application is the first application for continuing treatment with adalimumab, an assessment of the patient's response must be made following a minimum of 12 weeks of therapy so that there is adequate time for a response to be demonstrated.

The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with adalimumab.

Patients are eligible to receive continuing adalimumab treatment in courses of up to 24 weeks providing they continue to sustain the response.

A maximum of 24 weeks treatment will be authorised under this criterion.

Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday)

**Authority required**

Initial 3

Initial PBS-subsidised treatment of Crohn disease in a patient with short gut syndrome, an ostomy patient, or a patient with extensive small intestine disease, who has previously received non-PBS-subsidised therapy with adalimumab.

Initial PBS-subsidised supply for continuing treatment with adalimumab by a gastroenterologist, a consultant physician as specified in the NOTE below, or other consultant physician in consultation with a gastroenterologist, of a patient who:

(a) has a documented history of severe refractory Crohn disease and was receiving treatment with adalimumab prior to 9 November 2007; and
(b) (1) has a history of extensive small intestinal disease with radiological evidence of intestinal inflammation affecting more than 50 cm of the small intestine; or
(2) has diagnostic imaging or surgical evidence of short gut syndrome or has an ileostomy or colostomy with a documented history of intestinal inflammation; and
(c) has signed a patient acknowledgement indicating that they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and
(d) has demonstrated or sustained an adequate response to treatment with adalimumab according to the criteria included in the relevant continuation restriction. For advice please contact Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

The same criteria used to determine an inadequate response to prior treatment at baseline must be used to determine response to treatment and eligibility for continuing therapy, according to the criteria included in the continuing treatment restriction.

An adequate response to adalimumab treatment is defined as:
(a) a reduction in Crohn Disease Activity Index (CDAI) Score to no greater than 150; or
(b) improvement of intestinal inflammation as demonstrated by:
   (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; AND/OR
   (ii) faeces: normalisation of lactoferrin or calprotectin level; AND/OR
   (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or
   (c) reversal of high faecal output state; or
(d) avoidance of the need for surgery or total parenteral nutrition (TPN).

Applications for authorisation must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
   (i) the completed current and baseline Crohn Disease Activity Index (CDAI) Score calculation sheet, where relevant, including the date of the assessment of the patient's condition; or
   (2) the reports and dates of the current and baseline pathology or diagnostic imaging test(s) in order to assess response to therapy; or
   (3) the date of clinical assessment(s); and
   (ii) the signed patient acknowledgement.

The patient's assessment must be no more than 1 month old at the time of application. The baseline CDAI assessments must be from immediately prior to commencing treatment with adalimumab. Where a baseline assessment is not available, please call Medicare Australia on 1800 700 270 to discuss.

The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with adalimumab.

Patients 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

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 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 twice 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.

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

### adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges

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### adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes

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### 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 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 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 treatment period beyond 16 weeks.

  A PASI assessment of the patient's response to this course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with adalimumab. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

  It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised biological agent 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 [dosage (where applicable), date of commencement and duration of therapy]; and
   (iii) the signed patient and prescriber acknowledgements.

A maximum of 16 weeks of treatment with adalimumab will be authorised under this restriction.

Where fewer than 4 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period beyond 16 weeks.

A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with adalimumab.

In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised adalimumab treatment.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

**Authority required**

Initial or re-Treatment [Initial 2, Face, hand, foot (Received prior biological agent under PBS)]

Treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over who:

(a) have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot; and

(b) have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle; and

(c) have not failed PBS-subsidised therapy with adalimumab for the treatment of this condition in the current Treatment Cycle.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
   (i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and
   (ii) details of prior biological treatment, including dosage, date and duration of treatment.

Applications for patients who have demonstrated a response to PBS-subsidised adalimumab treatment within this Treatment Cycle 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...
ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

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).

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

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.
No applications for increased maximum quantities and/or repeats will be authorised.
Special Pricing Arrangements apply.

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges

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adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes

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**ADALIMUMAB**

**Authority required**
Active ankylosing spondylitis
Treatment Phase: Initial 1 (new patients)

**Clinical criteria:**
The condition must be radiographically (plain X-ray) confirmed Grade II bilateral sacroilitis or Grade III unilateral sacroilitis, **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 (ii) 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
For details on the appropriate minimum exercise program that will be accepted for the purposes of administering this restriction, please refer to the Department of Human Services website at www.humanservices.gov.au

**Authority required**
Ankylosing spondylitis
Treatment Phase: Initial 2 (change or recommencement for all patients)

**Clinical criteria:**
Patient must have a documented history of active ankylosing spondylitis, AND Patient must have received prior PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition in this treatment cycle, AND Patient must not have failed PBS-subsidised therapy with this drug for this condition in the current treatment cycle, AND Patient must be eligible to receive further bDMARD therapy.

**Population criteria:**
Patient must be an adult.

**Treatment criteria:**
Must be treated by a rheumatologist.
Where the most recent course of PBS-subsidised bDMARD treatment was approved under either of the initial treatment restrictions (i.e. for patients with no prior PBS-subsidised bDMARD therapy or, under this restriction, for patients who have received previous PBS-subsidised bDMARD therapy) the patient must have been assessed for response to that course following a minimum of 12 weeks of treatment. These assessments must be provided to the Department of Human Services no later than 4 weeks from the date the course was ceased. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.
Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, patients must have been assessed for response, and the assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
The authority application must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form.

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

Prescribing information (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. 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.

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 quality 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.

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

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 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges

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ADALIMUMAB

Authority required
Severe psoriatic arthritis
Treatment Phase: Initial treatment – Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more)

Clinical criteria:
- Patient must have severe active psoriatic arthritis, AND
- Patient must have received no prior PBS-subsidised treatment with a biological agent for this condition; OR
- Patient must have received no PBS-subsidised treatment with a biological agent for at least 5 years if they have previously received PBS-subsidised treatment with a biological agent for this condition, AND
- Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months, AND
- Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; OR
- Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months, AND
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:
- Patient must be an adult.

Treatment criteria:
- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab or infliximab.

Where treatment with methotrexate, sulfasalazine or leflunomide is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

Where intolerance to treatment with methotrexate, sulfasalazine or leflunomide developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:
- An elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; and
- Either
  (a) an active joint count of at least 20 active (swollen and tender) joints; or
  (b) at least 4 active joints from the following list of major joints:
    (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
    (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:
- (1) a completed authority prescription form; and
- (2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form; and
- (3) a signed patient acknowledgement.

Note
Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 3 months treatment with methotrexate and 3 months treatment with sulfasalazine or leflunomide can be found on the Department of Human Services website (www.humanservices.gov.au)

Authority required
Severe psoriatic arthritis
Treatment Phase: Initial treatment – Initial 2 (change or recommencement of treatment)

Clinical criteria:
- Patient must have a documented history of severe active psoriatic arthritis, AND
- Patient must have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle, AND
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological agents within this Treatment Cycle, AND
- Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug during the current Treatment Cycle, AND
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:
- Patient must be an adult.

Treatment criteria:
- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab or infliximab.

The authority application must be made in writing and must include:
ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

(1) a completed authority prescription form; and
(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

Applications for a patient who has previously received PBS-subsidised treatment with this drug within this Treatment Cycle and who wishes to recommence therapy with this drug within this same Cycle, must be accompanied by evidence of a response to the patient’s most recent course of PBS-subsidised treatment with this drug.

Where the most recent course of PBS-subsidised treatment was approved under either of the initial treatment restrictions (i.e. for patients with no prior PBS-subsidised biological therapy or, under this restriction, for patients who have received previous PBS-subsidised biological therapy), the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must have been submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment submitted no later than 4 weeks from the date that course was ceased.

Where a response assessment was not submitted within these timeframes, the patient will be deemed to have failed to respond to treatment.

An adequate response to treatment is defined as:

- an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and
- either of the following:
  - (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
  - (b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:
    - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
    - (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

**Note**

The assessment of the patient’s response to this initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted to the Department of Human Services no later than 4 weeks from the cessation of the treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

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

Prescribing information (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 SEVERE ACTIVE PSORIATIC ARTHRITIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, certolizumab pegol, etanercept, golimumab and infliximab for adult patients with severe active psoriatic arthritis.

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological agents at any 1 time.

Where the term ‘biological agents’ appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab and infliximab only.

Patients receiving PBS-subsidised treatment for psoriatic arthritis are able to commence a ‘Biological Treatment Cycle’ (Cycle), where they may trial biological agents without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological 3 agent as long as they sustain a response to therapy.

Following demonstration of response to initial treatment, these biological agents are available under the PBS for continuing treatment as set out in the continuing treatment restriction for each agent.

Once patients have either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological therapy before they are eligible to commence another Cycle [further details are under ‘(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy’ below].

The duration of the break in therapy will be measured from the date the last approval for PBS-subsidised treatment was granted in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Cycle.

Within the same Cycle, patients are not allowed to fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for any biological agent, they must change to an alternate agent which they have not previously failed, if they wish to continue PBS-subsidised biological treatment.

Patients for whom a break in PBS-subsidised therapy of less than 5 years has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.
Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle. There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe active psoriatic arthritis.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); and

(ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; and

(iii) patients wish to re-commence treatment with a specific biological agent following a break in PBS-subsidised therapy with that specific agent (Initial 2). All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept and golimumab, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), and 22 weeks of therapy for infliximab. It is recommended that patients be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological agent supply.

Patients must be assessed for response to any course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

Grandfather patients - certolizumab pegol only.

For patients who commenced treatment with certolizumab pegol for psoriatic arthritis prior to 1 April 2015, applications for initial PBS-subsidised treatment as continuing therapy may be made under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with any biological agent prior to PBS listing of that agent.

Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment for all agents. Approval will be based on the criteria included in the relevant restriction.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological agent, patients may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. Patients are eligible to receive continuing biological treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

Patients must be assessed for response to a course of continuing therapy, and the assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

(3) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate biological agent without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements.

Patients may swap to an alternate biological agent at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological agent at the time of the application or not. Within a Treatment Cycle patients may alternate between therapy with any biological agent of their choice (1 at a time) providing:

(i) they have not received PBS-subsidised treatment with that particular biological agent previously; or

(ii) they have demonstrated an adequate response to that particular biological agent if they have previously trialled it on the PBS; and

(iii) they have not previously failed to respond to treatment 3 times in this Treatment Cycle.

To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the biological agent the patient is ceasing.

(4) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the indices of disease severity submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment application is submitted within a treatment Cycle and these revised baseline measurements will be used to assess response.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

Patients who wish to trial a second or subsequent treatment Cycle following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment with respect to both the indices of disease severity. Patients must have received treatment with methotrexate and sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured.

Authority required

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more) or Initial 2 (change or recommencement of treatment) - balance of supply
ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Clinical criteria:
Patient must have received insufficient therapy with this drug under the Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more) restriction to complete 16 weeks treatment; OR
Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement of treatment) restriction to complete 16 weeks treatment. **AND**
The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Treatment criteria:
Must be treated by a rheumatologist; OR
Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Note**
No increase in the maximum quantity or number of units may be authorised.
No increase in the maximum number of repeats may be authorised.
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
GPO Box 9826
HOBART TAS 7001

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges

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**CERTOLIZUMAB PEGOL**

Authority required
Severe active rheumatoid arthritis
Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months).

Clinical criteria:
Patient must have severe active rheumatoid arthritis, **AND**
Patient must have received no PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition in the previous 24 months, **AND**
Patient must have not failed previous PBS-subsidised treatment with this drug for this condition, and have not already failed, or ceased to respond to, PBS-subsidised bDMARD treatment for this condition 5 times., **AND**
Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; **OR**
Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; **OR**
Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above, must include at least 3 months continuous treatment with each of at least 2 DMARDs, with one or more of the following DMARDs being used in place of the DMARDs which are contraindicated or not tolerated: (i) azathioprine at a dose of at least 1 mg/kg per day; and/or (ii) cyclosporin at a dose of at least 2 mg/kg/day; and/or (iii) sodium aurothiomalate at a dose of 50 mg weekly, **AND**
Patient must not receive more than 18 to 20 weeks of treatment, depending on the dosage regimen, under this restriction..

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

Treatment criteria:
Must be treated by a rheumatologist; OR
Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.
For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab or tocilizumab.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity. The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application.

The authority application must be made in writing and must include:

1. a completed authority prescription form;
2. a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form; and
3. a signed patient acknowledgement.

Assessment of a patient’s response to an initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

Applications for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient’s most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

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 a patient fails to demonstrate a response to treatment with this drug, must be accompanied by evidence of a response to the patient’s most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

- an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either
  1. (a) a total active joint count of at least 20 active (swollen and tender) joints; or
  2. (b) at least 4 active joints from the following list of major joints:
     1. (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
     2. (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

- The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Where the baseline joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP is provided with the initial application, the same marker will be used to determine response.

Note

The Department of Human Services website (www.humanservices.gov.au) has details of the toxicities, including severity, which will be accepted for the following purposes:

- (a) exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose;
- (b) substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial;
- (c) exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy.

Special Pricing Arrangements apply.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or re-commencement of treatment after break of less than 24 months).

Clinical criteria:

Patient must have a documented history of severe active rheumatoid arthritis, AND

Patient must have received prior PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition and are eligible to receive further bDMARD therapy, AND

Patient must not receive more than 18 to 20 weeks of treatment, depending on the dosage regimen, under this restriction.

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

**Treatment criteria:**
- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab or tocilizumab.

The authority application must be made in writing and must include:
(a) a completed authority prescription form and
(b) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

Application for a patient who has received PBS-subsidised treatment with this drug and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

If a patient fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

An adequate response to treatment is defined as:
- an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND
- either of the following:
  (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
  (b) a reduction in the number of the following active joints, from at least 4, by at least 50%:
    (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
    (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months) or Initial 2 (change or recommencement of treatment after break of less than 24 months) – balance of supply.

**Clinical criteria:**
- Patient must have received insufficient therapy with this drug under the Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months) restriction to complete 18 to 20 weeks treatment, depending on the dosage regimen; OR
- Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement of treatment after break of less than 24 months) restriction to complete 18 to 20 weeks treatment, depending on the dosage regimen, AND

The treatment must provide no more than the balance of up to 18 to 20 weeks treatment available under the above restrictions.

**Treatment criteria:**
- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Note**

Authority approval for sufficient therapy to complete a maximum of 18-20 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 18-20 weeks of treatment should be forwarded to:

Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826

HOBART TAS 7001

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Continuing treatment

**Clinical criteria:**
- Patient must have a documented history of severe active rheumatoid arthritis, AND
- Patient must have demonstrated an adequate response to treatment with this drug, AND
Patient must have received this drug as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment, AND

Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

**Population criteria:**

Patient must be aged 18 years or older.

**Treatment criteria:**

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab or tocilizumab.

An adequate response to treatment is defined as:

- an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

All applications for continuing treatment with this drug must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**Note**

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

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

Applications for authority to prescribe should be forwarded to: Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

**HOBART TAS 7001**

**TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab) and the T-cell co-stimulation modulator (abatacept).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:

- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy;

- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and

- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for
treatment under the Initial 1 treatment restriction. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010:
(a) Initial treatment.

Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab and tocilizumab, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks. Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:

Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient’s weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:

A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD 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 switch to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept patients:

Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of
rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

the Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

**Authority required**

Severe active rheumatoid arthritis

**Treatment Phase: Continuing Treatment – balance of supply.**

**Clinical criteria:**

Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, **AND**

The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Treatment criteria:**

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Note**

Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:

Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826

HOBART TAS 7001

certolizumab pegol 200 mg/mL injection, 2 x 1 mL syringes

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**CERTOLIZUMAB PEGOL**

**Authority required**

Active ankylosing spondylitis

**Treatment Phase: Initial 1 (new patients)**

**Clinical criteria:**

The condition must be radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis, **AND**

Patient must not have received any PBS-subsidised treatment with either adalimumab, certolizumab pegol, etanercept, golimumab or infliximab in this treatment cycle, **AND**

Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; or (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); or (iii) limitation of chest expansion relative to normal values for age and gender. **AND**

Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months.

**Population criteria:**

Patient must be an adult.

**Treatment criteria:**

Must be treated by a rheumatologist.

The application must include details of the NSAIDs trialled, their doses and duration of treatment.
If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used.

If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication.

If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance.

The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application:

(a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; AND

(b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L.

The BASDAI must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. The BASDAI must be no more than 1 month old at the time of initial application.

Both ESR and CRP measures should be provided with the initial treatment application and both must be no more than 1 month old. If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form which must include the following:

(i) a copy of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and

(ii) a completed BASDAI Assessment Form; and

(iii) a completed Exercise Program Self Certification Form included in the supporting information form; and

(iv) a signed patient acknowledgment.

The assessment of the patient's response to the initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted no later than 4 weeks from the cessation of that treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

A maximum of 18 to 20 weeks of treatment with this drug will be approved under this criterion.

Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) was approved in this cycle and the date of the first application under a new cycle.

Note
Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Department of Human Services website at www.humanservices.gov.au

For details on the appropriate minimum exercise program that will be accepted for the purposes of administering this restriction, please refer to the Department of Human Services website at www.humanservices.gov.au

Authority required
Ankylosing spondylitis
Treatment Phase: Initial 2 (change or recommencement for all patients)

Clinical criteria:
Patient must have a documented history of active ankylosing spondylitis, AND
Patient must have received prior PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition in this treatment cycle, AND
Patient must not have failed PBS-subsidised therapy with this drug 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 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.

Authority required
Antilyosing 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, antilyosing 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
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 antilyosing 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
Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (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
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 next 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.

(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 equally 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.

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

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

certolizumab pegol 200 mg/mL injection, 2 x 1 mL syringes

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**CERTOLIZUMAB PEGOL**

**Authority required**

Severe psoriatic arthritis

Treatment Phase: Initial treatment – Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more)

**Clinical criteria:**

Patient must have severe active psoriatic arthritis, **AND**

Patient must have received no prior PBS-subsidised treatment with a biological agent for this condition; OR

Patient must have received no PBS-subsidised treatment with a biological agent for at least 5 years if they have previously received PBS-subsidised treatment with a biological agent for this condition, **AND**

Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months, **AND**

Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; OR

Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months, **AND**

Patient must not receive more than 18 to 20 weeks of treatment, depending on the dosage regimen, under this restriction.

**Population criteria:**

Patient must be an adult.

**Treatment criteria:**

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

For the purposes of this restriction ‘biological agent’ means adalimumab, certolizumab pegol, etanercept, golimumab or infliximab.
Where treatment with methotrexate, sulfasalazine or leflunomide is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

Where intolerance to treatment with methotrexate, sulfasalazine or leflunomide developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

- an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; and
- either
  - (a) an active joint count of at least 20 active (swollen and tender) joints; or
  - (b) at least 4 active joints from the following list of major joints:
    - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
    - (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:
- (1) a completed authority prescription form; and
- (2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form; and
- (3) a signed patient acknowledgement.

**Note**
Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 3 months treatment with methotrexate and 3 months treatment with sulfasalazine or leflunomide can be found on the Department of Human Services website (www.humanservices.gov.au)

**Authority required**
Serious psoriatic arthritis
Treatment Phase: Initial treatment – Initial 2 (change or recommencement of treatment)

**Clinical criteria:**
- Patient must have a documented history of severe active psoriatic arthritis, **AND**
- Patient must have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological agents within this Treatment Cycle, **AND**
- Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug during the current Treatment Cycle, **AND**
- Patient must not receive more than 18 to 20 weeks of treatment, depending on the dosage regimen, under this restriction.

**Population criteria:**
- Patient must be an adult.

**Treatment criteria:**
- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab or infliximab.

The authority application must be made in writing and must include:
- (1) a completed authority prescription form; and
- (2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

Applications for a patient who has previously received PBS-subsidised treatment with this drug within this Treatment Cycle and who wishes to recommence therapy with this drug within this same Cycle, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug.

Where the most recent course of PBS-subsidised treatment was approved under either of the initial treatment restrictions (i.e. for patients with no prior PBS-subsidised biological therapy or, under this restriction, for patients who have received previous PBS-subsidised biological therapy), the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must have been submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment submitted no later than 4 weeks from the date that course was ceased.

Where a response assessment was not submitted within these timeframes, the patient will be deemed to have failed to respond to treatment.

An adequate response to treatment is defined as:
- an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and
- either of the following:
  - (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
  - (b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:
    - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
(iii) 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).

**Authority required**
Severe psoriatic arthritis

**Treatment Phase:** Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more) or Initial 2 (change or recommencement of treatment) - balance of supply

**Clinical criteria:**
Patient must have received insufficient therapy with this drug under the Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more) restriction to complete 18 to 20 weeks treatment; OR
Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement of treatment) restriction to complete 18 to 20 weeks treatment. **AND**
The treatment must provide no more than the balance of up to 18 to 20 weeks treatment available under the above restrictions.

**Treatment criteria:**
Must be treated by a rheumatologist; **OR**
Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Note**
Authority approval for sufficient therapy to complete a maximum of 18 to 20 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 18 to 20 weeks of treatment should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826

HOBART TAS 7001

**Authority required**
Severe psoriatic arthritis

**Treatment Phase:** Initial treatment - Initial 3 (initial PBS-subsidised supply for continuing treatment in a patient commenced on non-PBS-subsidised therapy)

**Clinical criteria:**
Patient must have a documented history of severe active psoriatic arthritis, **AND**
Patient must have been receiving treatment with certolizumab pegol for this condition prior to 1 April 2015, **AND**
Patient must be receiving treatment with certolizumab pegol at the time of application, **AND**
Patient must have demonstrated a response to treatment as specified in the criteria for continuing PBS-subsidised treatment with certolizumab pegol, **AND**
Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**
Patient must be an adult.

**Treatment criteria:**
Must be treated by a rheumatologist; **OR**
Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

The authority application must be made in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form; and
(3) a signed patient acknowledgement.

A patient may qualify for PBS-subsidised treatment under this restriction once only.

**Note**
The assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted to the Department of Human Services no later than 4 weeks from the cessation of the treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

**Authority required**
Severe psoriatic arthritis

**Treatment Phase:** Initial treatment - Initial 3 (initial PBS-subsidised supply for continuing treatment in a patient commenced on non-PBS-subsidised therapy) - balance of supply

**Clinical criteria:**
Patient must have received insufficient therapy with this drug under the Initial 3 (initial PBS-subsidised supply for continuing treatment in a patient commenced on non-PBS-subsidised therapy) restriction to complete 24 weeks treatment, **AND**
The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Treatment criteria:**
Must be treated by a rheumatologist; **OR**
Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.
Severe psoriatic arthritis  
Treatment Phase: Continuing treatment  
Clinical criteria:  
Patient must have a documented history of severe active psoriatic arthritis, AND 
Patient must have received this drug as their most recent course of PBS-subsidised treatment with a biological agent for this condition in the current Treatment Cycle, AND 
Patient must demonstrate, at the time of application, an adequate response to treatment with this drug, AND 
Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.  
Population criteria:  
Patient must be an adult.  
Treatment criteria:  
Must be treated by a rheumatologist; OR  
Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.  
For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab or infliximab.  
An adequate response to treatment is defined as:  
an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and  
either of the following:  
(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or  
(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:  
(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or  
(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).  
The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications.  
All applications for continuing treatment with this drug must include a measurement of response to the most recent course of PBS-subsidised therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with the initial treatment course.  
Where a response assessment is not submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.  
The authority application must be made in writing and must include:  
(1) a completed authority prescription form; and  
(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form.  
Note  
Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.  
Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).  
Prescribing information (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 SEVERE ACTIVE PSORIATIC ARTHRITIS  
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, certolizumab pegol, etanercept, golimumab and infliximab for adult patients with severe active psoriatic arthritis.  
Patients are eligible for PBS-subsidised treatment with only 1 of the above biological agents at any 1 time.  
Where the term 'biological agents' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab and infliximab only.  
Patients receiving PBS-subsidised treatment for psoriatic arthritis are able to commence a ‘Biological Treatment Cycle’ (Cycle), where they may trial biological agents without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.  
Following demonstration of response to initial treatment, these biological agents are available under the PBS for continuing treatment as set out in the continuing treatment restriction for each agent.  
Once patients have either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological therapy before they are eligible to commence another Cycle [further details are under '(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' below].
The duration of the break in therapy will be measured from the date the last approval for PBS-subsidised treatment was granted in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Cycle.

Within the same Cycle, patients are not allowed to fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for any biological agent, they must change to an alternate agent which they have not previously failed, if they wish to continue PBS-subsidised biological treatment.

Patients for whom a break in PBS-subsidised therapy of less than 5 years has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle.

There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe active psoriatic arthritis.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); and
(ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; and
(iii) patients wish to re-commence treatment with a specific biological agent following a break in PBS-subsidised therapy with that specific agent (Initial 2).

All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept and golimumab, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), and 22 weeks of therapy for infliximab. It is recommended that patients be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological agent supply.

Patients must be assessed for response to any course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

Grandfather patients - certolizumab pegol only.

For patients who commenced treatment with certolizumab pegol for psoriatic arthritis prior to 1 April 2015, applications for initial PBS-subsidised treatment as continuing therapy may be made under the relevant initial treatment restriction (Initial 3).

These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with any biological agent prior to PBS listing of that agent.

Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment for all agents. Approval will be based on the criteria included in the relevant restriction.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological agent, patients may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

Patients are eligible to receive continuing biological treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

Patients may be assessed for response to a course of continuing therapy, and the assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

(3) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate biological agent without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements.

Patients may swap to an alternate biological agent at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological agent at the time of the application or not.

Within a Treatment Cycle patients may alternate between therapy with any biological agent of their choice (1 at a time) providing:

(i) they have not received PBS-subsidised treatment with that particular biological agent previously; or
(ii) they have demonstrated an adequate response to that particular biological agent if they have previously trialled it on the PBS; and
(iii) they have not previously failed to respond to treatment 3 times in this Treatment Cycle.

To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the biological agent the patient is ceasing.

(4) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the indices of disease severity submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment application is submitted within a treatment Cycle and these revised baseline measurements will be used to assess response.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.
Patients who wish to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment with respect to both the indices of disease severity. Patients must have received treatment with methotrexate and sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured.

**Authority required**

Severe psoriatic arthritis

Treatment Phase: Continuing treatment - balance of supply

**Clinical criteria:**

Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment. **AND**

The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Treatment criteria:**

Must be treated by a rheumatologist; **OR**

Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Note**

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

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

Special Pricing Arrangements apply.

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

certolizumab pegol 200 mg/mL injection, 2 x 1 mL syringes

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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:

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 who has a break in therapy of more than 24 months must commence a new treatment cycle. The length of the break in therapy is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or

(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or

(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24...
weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. A patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count and ESR/CRP) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle. To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.

(4) Re-commencement of treatment after a 24 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 24 months, must requalify for treatment under the Initial 1 treatment restriction.

**Authority required**

Severe active juvenile idiopathic arthritis

**Treatment Phase:** Continuing treatment – balance of supply

**Clinical criteria:**

Patient must have received insufficient etanercept therapy under the Continuing treatment restriction to complete 24 weeks treatment, AND

The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Treatment criteria:**

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Note**

Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

**ETANERCEPT Injection 50 mg in 1 mL single use auto-injector, 4, 1**

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**ETANERCEPT Injections 50 mg in 1 mL single use pre-filled syringes, 4, 1**

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

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**ETANERCEPT**

**Authority required**

Severe active rheumatoid arthritis
Schedule of Pharmaceutical Benefits

TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alpha antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab or tocilizumab).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alpha antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:

- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDS for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alpha antagonists prior to 1 August 2010 please provide with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

- a completed authority prescription form; and
- a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

All applications for continuing treatment with this drug must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note

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

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

Applications for authority to prescribe should be forwarded to: Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

HOBART TAS 7001

TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alpha antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab) and the T-cell co-stimulation modulator (abatacept).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alpha antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:

- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDS for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alpha antagonists prior to 1 August 2010 please...
Contact the Department of Human Services on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

1. How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) A patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or

(ii) A patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or

(iii) A patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or

(iv) A patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab and tocilizumab, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For a second and subsequent courses of PBS-subsidised treatment (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:

Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient’s weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:

A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with the agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

2. Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept patients:

Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised therapy.
TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

**Authority required**
Severe active rheumatoid arthritis
Treatment Phase: Continuing Treatment – balance of supply

**Clinical criteria:**
Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, AND

The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Treatment criteria:**
Must be treated by a rheumatologist; OR
Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Note**
Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826

HOBART TAS 7001

**ETANERCEPT Injection 50 mg in 1 mL single use auto-injector, 4, 1**

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**ETANERCEPT Injections 50 mg in 1 mL single use pre-filled syringes, 4, 1**

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

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**ETANERCEPT**

**Authority required**
Continuing treatment (Whole body)
Continuing PBS-subsidised treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over:
(a) who have a documented history of severe chronic plaque psoriasis; and
(b) whose most recent course of PBS-subsidised biological treatment for this condition in this Treatment Cycle was with etanercept; and
(c) who have demonstrated an adequate response to their most recent course of treatment with etanercept.

An adequate response to treatment is defined as:
A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the pre-biological treatment baseline value for this Treatment Cycle.

This assessment must be provided to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with etanercept, the assessment of response must be after a minimum of 12 weeks of treatment with an initial course. Applications for authorisation must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) the completed Psoriasis Area and Severity Index (PASI) calculation sheet along with the date of the assessment of the patient's condition.
The most recent PASI assessment must be no more than 1 month old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with etanercept.

A maximum of 24 weeks of treatment with etanercept will be authorised under this restriction.

Where fewer than 5 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for continuing authority applications, or for treatment that would otherwise extend the treatment period beyond 24 weeks.

A PASI assessment of the patient's response must be conducted within 4 weeks prior to completion of this course of treatment. This assessment must be submitted to Medicare Australia no later than 1 month from the date of completion of this course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with etanercept. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised etanercept treatment.

Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may re-commence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

**Authority required**

Continuing treatment (Face, hand, foot)

Continuing PBS-subsidised treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over:
(a) who have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot; and
(b) whose most recent course of PBS-subsidised biological treatment for this condition in this Treatment Cycle was with etanercept; and
(c) who have demonstrated an adequate response to treatment with etanercept.

An adequate response to etanercept treatment is defined as the plaque or plaques assessed prior to biological treatment showing:
(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the pre-biological treatment baseline values; or
(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the pre-biological treatment baseline value.

This assessment must be provided to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with etanercept, the assessment of response must be after a minimum of 12 weeks of treatment with an initial course.

Applications for authorisation must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams along with the date of the assessment of the patient's condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

The most recent PASI assessment must be no more than 1 month old at the time of application.

A maximum of 24 weeks of treatment with etanercept will be authorised under this restriction.

Where fewer than 5 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for continuing authority applications, or for treatment that would otherwise extend the treatment period beyond 24 weeks.
A PASI assessment of the patient’s response must be conducted within 4 weeks prior to completion of this course of treatment. This assessment must be submitted to Medicare Australia no later than 1 month from the date of completion of this course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with etanercept. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised etanercept treatment.

The PASI assessment for continuing treatment must be performed on the same affected area assessed at baseline. Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may re-commence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

Note

Any queries concerning the arrangements to prescribe etanercept may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe etanercept should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826

HOBART TAS 7001

TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLACED 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 approval for 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.

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.

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

Special Pricing Arrangements apply.

**ETANERCEPT Injection 50 mg in 1 mL single use auto-injector, 4, 1**

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**ETANERCEPT Injections 50 mg in 1 mL single use pre-filled syringes, 4, 1**

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

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**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 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 in the application, the application must include 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
- (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.
**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 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**

**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:

1. continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and
2. 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 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

ETANERCEPT Injection 50 mg in 1 mL single use auto-injector, 4, 1
3447K
Max.Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer
1 3 .. 1774.71 37.70 Enbrel [PF]

ETANERCEPT Injections 50 mg in 1 mL single use pre-filled syringes, 4, 1
3446J
Max.Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer
1 3 .. 1774.71 37.70 Enbrel [PF]

etanercept 25 mg injection [4 x 25 mg vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack
3445H
Max.Qty Packs No. of Rpts Premium $ DPMQ $ MRVSN $ Brand Name and Manufacturer
2 3 .. *1774.70 37.70 Enbrel [PF]

ETANERCEPT

Authority required
Ankylosing spondylitis
Treatment Phase: Continuing treatment

Clinical criteria:
Patient must have a documented history of active ankylosing spondylitis, AND
Patient must have received this drug as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment in this treatment cycle, AND
Patient must have demonstrated an adequate response to treatment with this drug.

Population criteria:
Patient must be an adult.

Treatment criteria:
Must be treated by a rheumatologist.
An adequate response is defined as an improvement from baseline of at least 2 of the BASDAI and 1 of the following: (a) an ESR measurement no greater than 25 mm per hour; or (b) a CRP measurement no greater than 10 mg per L; or (c) an ESR or CRP measurement reduced by at least 20% from baseline.
Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and supplied in all subsequent continuing treatment applications.
The authority application must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form.
All measurements provided must be no more than 1 month old at the time of application.
A maximum of 24 weeks of treatment with this drug will be authorised under this criterion.
All applications for continuing treatment with this drug must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment following an initial treatment course it must be made following a minimum of 12 weeks of treatment with this drug. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.
Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last 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

TREATMENT OF ADULT PATIENTS WITH ACTIVEankylosing SPONDYLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, certolizumab pegol, etanercept, golimumab and infliximab for adult patients with active ankylosing spondylitis.

Where the term ‘bDMARD’ appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 5 bDMARDs at any 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: 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.
- No increase in the maximum number of repeats may be authorised.

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 Injection 50 mg in 1 mL single use auto-injector, 4, 1**

9456Q

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**ETANERCEPT Injections 50 mg in 1 mL single use pre-filled syringes, 4, 1**

9086F

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

8779C

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**ETANERCEPT**

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months)

**Clinical criteria:**

- Patient must have severe active rheumatoid arthritis, **AND**
- Patient must have received no PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition in the previous 24 months, **AND**
Patient must not have failed previous PBS-subsidised treatment with this drug for this condition, and have not already failed, or ceased to respond to, PBS-subsidised bDMARD treatment for this condition 5 times, AND

Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR

Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR

Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above, must include at least 3 months continuous treatment with each of at least 2 DMARDs, with one or more of the following DMARDs being used in place of the DMARDs which are contraindicated or not tolerated: (i) azathioprine at a dose of at least 1 mg/kg per day; and/or (ii) cyclosporin at a dose of at least 2 mg/kg/day; and/or (iii) sodium aurothiomalate at a dose of 50 mg weekly, AND

Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

Patient must be aged 18 years or older.

**Treatment criteria:**

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab or tocilizumab.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application.

The authority application must be made in writing and must include:

1. A completed authority prescription form; and
2. A completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form; and
3. A signed patient acknowledgement.

Assessment of a patient's response to an initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

Applications for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

- an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either
  - (a) a total active joint count of at least 20 active (swollen and tender) joints; or
  - (b) at least 4 active joints from the following list of major joints:
    - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
    - (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.
If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.
Where the baseline joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP is provided with the initial application, the same marker will be used to determine response.

**Note**
The Department of Human Services website (www.humanservices.gov.au) has details of the toxicities, including severity, which will be accepted for the following purposes:
(a) exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose;
(b) substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial;
(c) exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy.

Special Pricing Arrangements apply.

**Authority required**
Severe active rheumatoid arthritis

**Treatment Phase:** Initial treatment - Initial 2 (change or re-commencement of treatment after break of less than 24 months)

**Clinical criteria:**
Patient must have a documented history of severe active rheumatoid arthritis, **AND**
Patient must have received prior PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition and are eligible to receive further bDMARD therapy, **AND**
Patient must not receive more than 16 weeks of treatment under this restriction.

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

**Treatment criteria:**
Must be treated by a rheumatologist; OR
Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab or tocilizumab.

The authority application must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

Applications for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to a treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD

An adequate response to treatment is defined as:
an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

**AND** either of the following:
(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:
(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

**Note**
Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to: Department of Human Services

Prior Written Approval of Complex 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 antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alpha antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab) and the T-cell co-stimulation modulator (abatacept).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any one time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:

- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy;
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction.

A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab and tocilizumab, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:

Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient’s weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:

A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services.
no later than 4 weeks from the date that course was ceased.

Rituximab patients:
A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent bDMARD treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept patients:
Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD.

However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months) or Initial 2 (change or recommencement of treatment after break of less than 24 months) – balance of supply.

**Clinical criteria:**

Patient must have received insufficient therapy with this drug under the Initial 1 (new patient or patient recommencing treatment after break of more than 24 months) restriction to complete 16 weeks treatment; OR

Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement of treatment after break of less than 24 months) restriction to complete 16 weeks treatment, AND

The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Treatment criteria:**

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Note**

Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:
**ETANERCEPT**

**Authority required**

Severe psoriatic arthritis

**Clinical criteria:**

Patient must have a documented history of severe active psoriatic arthritis, **AND**

Patient must have received this drug as their most recent course of PBS-subsidised treatment with a biological agent for this condition in the current Treatment Cycle, **AND**

Patient must demonstrate, at the time of application, an adequate response to treatment with this drug, **AND**

Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

**Population criteria:**

Patient must be an adult.

**Treatment criteria:**

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab or infliximab.

An adequate response to treatment is defined as:

- an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

- either of the following:
  1. a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
  2. a reduction in the number of the following major active joints, from at least 4, by at least 50%:
     - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
     - (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

- The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications.

- All applications for continuing treatment with this drug must include a measurement of response to the most recent course of PBS-subsidised therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with the initial treatment course.

- Where a response assessment is not submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

- The authority application must be made in writing and must include:
  1. a completed authority prescription form; and
  2. a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

**Note**

Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

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

Prescribing information (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 SEVERE ACTIVE PSORIATIC ARTHRITIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, certolizumab pegol, etanercept, golimumab and infliximab for adult patients with severe active psoriatic arthritis.

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological agents at any 1 time. Where the term ‘biological agents’ appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab and infliximab only.

Patients receiving PBS-subsidised treatment for psoriatic arthritis are able to commence a ‘Biological Treatment Cycle’ (Cycle), where they may trial biological agents without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

Following demonstration of response to initial treatment, these biological agents are available under the PBS for continuing treatment as set out in the continuing treatment restriction for each agent.

Once patients have either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological therapy before they are eligible to commence another Cycle [further details are under ‘(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy’ below].

The duration of the break in therapy will be measured from the date the last approval for PBS-subsidised treatment was granted in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Cycle.

Within the same Cycle, patients are not allowed to fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for any biological agent, they must change to an alternate agent which they have not previously failed, if they wish to continue PBS-subsidised biological treatment.

Patients for whom a break in PBS-subsidised therapy of less than 5 years has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle. There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe active psoriatic arthritis.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); and

(ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; and

(iii) patients wish to re-commence treatment with a specific biological agent following a break in PBS-subsidised therapy with that specific agent (Initial 2).

All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept and golimumab, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), and 22 weeks of therapy for infliximab. It is recommended that patients be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological agent supply.

Patients must be assessed for response to any course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

Grandfather patients - certolizumab pegol only.

For patients who commenced treatment with certolizumab pegol for psoriatic arthritis prior to 1 April 2015, applications for initial PBS-subsidised treatment as continuing therapy may be made under the relevant initial treatment restriction (Initial 3).

These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with any biological agent prior to PBS listing of that agent.

Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment for all agents. Approval will be based on the criteria included in the relevant restriction.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological agent, patients may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. Patients are eligible to receive continuing biological treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

Patients must be assessed for response to a course of continuing therapy, and the assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

(3) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate biological agent without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements.

Patients may swap to an alternate biological agent at any time, regardless of whether they are receiving therapy (initial or...
continuing) with a biological agent at the time of the application or not. Within a Treatment Cycle patients may alternate between therapy with any biological agent of their choice (1 at a time) providing:

(i) they have not received PBS-subsidised treatment with that particular biological agent previously; or
(ii) they have demonstrated an adequate response to that particular biological agent if they have previously trialled it on the PBS; and
(iii) they have not previously failed to respond to treatment 3 times in this Treatment Cycle.

To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the biological agent the patient is ceasing.

(4) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the indices of disease severity submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment application is submitted within a Treatment Cycle and these revised baseline measurements will be used to assess response.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

Patients who wish to trial a second or subsequent treatment Cycle following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment with respect to both the indices of disease severity. Patients must have received treatment with methotrexate and sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured.

**Authority required**

Severe psoriatic arthritis  
Treatment Phase: Continuing treatment - balance of supply  
**Clinical criteria:**  
Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, AND  
The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.  
**Treatment criteria:**  
Must be treated by a rheumatologist; OR  
Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

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

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 Injection 50 mg in 1 mL single use auto-injector, 4, 1**

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**ETANERCEPT Injections 50 mg in 1 mL single use pre-filled syringes, 4, 1**

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

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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 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 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 etanercept for 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.

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 [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 to discuss.
700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period beyond 16 weeks.

A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with etanercept. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised etanercept treatment.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

**Authority required**

**Initial or Re-Treatment**

| Treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over who: |
| (a) have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot; and |
| (b) have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle; and |
| (c) have not failed PBS-subsidised therapy with etanercept for the treatment of this condition in the current Treatment Cycle. |

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient’s condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and

(ii) details of prior biological treatment, including dosage, date and duration of treatment.

Applications for patients who have demonstrated a response to PBS-subsidised etanercept treatment within this Treatment Cycle and who wish to re-commence etanercept treatment within the same Cycle following a break in therapy, will only be approved where evidence of the patient's response to their most recent course of PBS-subsidised etanercept treatment has been submitted to Medicare Australia within 1 month of cessation of treatment.

A maximum of 16 weeks of treatment with etanercept will be authorised under this restriction.

Where fewer than 3 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period beyond 16 weeks.

A PASI assessment of the patient's response to this course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with etanercept. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised etanercept treatment.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline. Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may re-commence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

**Note**

Any queries concerning the arrangements to prescribe etanercept may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe etanercept should be forwarded to:
Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

**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:

- patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); or
- 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
- patients who wish to re-commence treatment following a break in PBS-subsidised therapy with that agent (Initial 2).

All applications for initial treatment will be limited to provide for a maximum of 16 weeks of treatment in the case of adalimumab and etanercept, 22 weeks of treatment in the case of infliximab and 28 weeks of treatment in the case of ustekinumab.


When prescribing initial treatment with a biological agent, a PASI assessment must be conducted after at least 12 weeks of treatment. This assessment must be submitted to Medicare Australia within 1 month of the completion of this initial treatment course. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. 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.


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.

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS
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.

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

Special Pricing Arrangements apply.

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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:
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.

Population 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.

Clinical criteria:
- 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.

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 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.

For details on the appropriate minimum exercise program that will be accepted for the purposes of administering this restriction, please refer to the Department of Human Services website at www.humanservices.gov.au.

Authority required
Ankylosing spondylitis
Treatment Phase: Initial 2 (change or recommencement for all patients)

Clinical criteria:
- Patient must have a documented history of active ankylosing spondylitis, AND
- Patient must have received prior PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition in this treatment cycle, AND
- Patient must not have failed PBS-subsidised therapy with this drug for this condition in the current treatment cycle, AND
- Patient must be eligible to receive further bDMARD therapy.

Population criteria:
- Patient must be an adult.

Treatment criteria:
- Must be treated by a rheumatologist.
- Where the most recent course of PBS-subsidised bDMARD treatment was approved under either of the initial treatment restrictions (i.e. for patients with no prior PBS-subsidised bDMARD therapy or, under this restriction, for patients who have received previous PBS-subsidised bDMARD therapy) the patient must have been assessed for response to that course following a minimum of 12 weeks of treatment. These assessments must be provided to the Department of Human Services no later than 4 weeks from the date the course was ceased. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.
- Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, patients must have been assessed for response, and the assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
- The authority application must be made in writing and must include:
  (a) a completed authority prescription form; and
  (b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form.
- A maximum of 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
Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (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 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 cycle.

(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.
Antineoplastic and Immunomodulating Agents

Schedule of Pharmaceutical Benefits

General

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

ETANERCEPT Injection 50 mg in 1 mL single use auto-injector, 4, 1
9455P

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ETANERCEPT Injections 50 mg in 1 mL single use pre-filled syringes, 4, 1
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etanercept 25 mg injection [4 x 25 mg vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack
8778B

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- ETANERCEPT

Authority required
Severe psoriatic arthritis
Treatment Phase: Initial treatment – Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more)

Clinical criteria:
Patient must have severe active psoriatic arthritis, AND
Patient must have received no prior PBS-subsidised treatment with a biological agent for this condition; OR
Patient must have received no PBS-subsidised treatment with a biological agent for at least 5 years if they have previously received PBS-subsidised treatment with a biological agent for this condition, AND
Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months, AND
Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; OR
Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months, AND
Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:
Patient must be an adult.

Treatment criteria:
Must be treated by a rheumatologist; OR
Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.
For the purposes of this restriction ‘biological agent’ means adalimumab, certolizumab pegol, etanercept, golimumab or infliximab.
Where treatment with methotrexate, sulfasalazine or leflunomide is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.
Where intolerance to treatment with methotrexate, sulfasalazine or leflunomide developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

- an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; and
- either
  - (a) an active joint count of at least 20 active (swollen and tender) joints; or
  - (b) at least 4 active joints from the following list of major joints:
    - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
    - (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:

1. a completed authority prescription form; and
2. a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form; and
3. a signed patient acknowledgement.

### Note
Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 3 months treatment with methotrexate and 3 months treatment with sulfasalazine or leflunomide can be found on the Department of Human Services website (www.humanservices.gov.au)

### Authority required
Severe psoriatic arthritis

**Treatment Phase:** Initial treatment – Initial 2 (change or recommencement of treatment)

**Clinical criteria:**
- Patient must have a documented history of severe active psoriatic arthritis, **AND**
- Patient must have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological agents within this Treatment Cycle, **AND**
- Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug during the current Treatment Cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**
- Patient must be an adult.

**Treatment criteria:**
- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab or infliximab.

The authority application must be made in writing and must include:

1. a completed authority prescription form; and
2. a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

Applications for a patient who has previously received PBS-subsidised treatment with this drug within this Treatment Cycle and who wishes to recommence therapy with this drug within this same Cycle, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug.

Where the most recent course of PBS-subsidised treatment was approved under either of the initial treatment restrictions (i.e. for patients with no prior PBS-subsidised biological therapy or, under this restriction, for patients who have received previous PBS-subsidised biological therapy), the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must have been submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment submitted no later than 4 weeks from the date that course was ceased.

Where a response assessment was not submitted within these timeframes, the patient will be deemed to have failed to respond to treatment.

An adequate response to treatment is defined as:

- an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and
- either
  - (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
  - (b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:
    - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
    - (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).
Note

The assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted to the Department of Human Services no later than 4 weeks from the cessation of the treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

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

Prescribing information (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 SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, certolizumab pegol, etanercept, golimumab and infliximab for adult patients with severe active psoriatic arthritis.

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological agents at any 1 time. Where the term 'biological agents' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab and infliximab only.

Patients receiving PBS-subsidised treatment for psoriatic arthritis are able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

Following demonstration of response to initial treatment, these biological agents are available under the PBS for continuing treatment as set out in the continuing treatment restriction for each agent.

Once patients have either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological therapy before they are eligible to commence another Cycle [further details are under '(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' below].

The duration of the break in therapy will be measured from the date the last approval for PBS-subsidised treatment was granted in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Cycle.

Within the same Cycle, patients are not allowed to fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for any biological agent, they must change to an alternate agent which they have not previously failed, if they wish to continue PBS-subsidised biological treatment.

Patients for whom a break in PBS-subsidised therapy of less than 5 years has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle.

There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe active psoriatic arthritis.

(1) Initial treatment.

Applications for initial treatment should be made where:
(i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); and
(ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; and
(iii) patients wish to re-commence treatment with a specific biological agent following a break in PBS-subsidised therapy with that specific agent (Initial 2).

All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept and golimumab, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), and 22 weeks of therapy for infliximab. It is recommended that patients be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological agent supply.

Patients must be assessed for response to any course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

Grandfather patients - certolizumab pegol only.

For patients who commenced treatment with certolizumab pegol for psoriatic arthritis prior to 1 April 2015, applications for initial PBS-subsidised treatment as continuing therapy may be made under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with any biological agent prior to PBS listing of that agent.

Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment for all agents. Approval will be based on the criteria included in the relevant restriction.
(2) Continuing treatment.
Following the completion of an initial treatment course with a specific biological agent, patients may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.
Patients are eligible to receive continuing biological treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
Patients must be assessed for response to a course of continuing therapy, and the assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.
(3) Swapping therapy.
Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate biological agent without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements.
Patients may swap to an alternate biological agent at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological agent at the time of the application or not.
Within a Treatment Cycle patients may alternate between therapy with any biological agent of their choice (1 at a time) providing:
(i) they have not received PBS-subsidised treatment with that particular biological agent previously; or
(ii) they have demonstrated an adequate response to that particular biological agent if they have previously trialled it on the PBS; and
(iii) they have not previously failed to respond to treatment 3 times in this Treatment Cycle.
To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the biological agent the patient is ceasing.
(4) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the indices of disease severity submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment application is submitted within a treatment Cycle and these revised baseline measurements will be used to assess response.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.
(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.
Patients who wish to trial a second or subsequent treatment Cycle following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment with respect to both the indices of disease severity. Patients must have received treatment with methotrexate and sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured.

**Authority required**
Severe psoriatic arthritis
Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more) or Initial 2 (change or recommencement of treatment) - balance of supply

**Clinical criteria:**
Patient must have received insufficient therapy with this drug under the Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more) restriction to complete 16 weeks treatment; OR
Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement of treatment) restriction to complete 16 weeks treatment, AND
The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Treatment criteria:**
Must be treated by a rheumatologist; OR
Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Note**
No increase in the maximum quantity or number of units may be authorised.
No increase in the maximum number of repeats may be authorised.
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
ETANERCEPT Injection 50 mg in 1 mL single use auto-injector, 4, 1
9457R

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ETANERCEPT Injections 50 mg in 1 mL single use pre-filled syringes, 4, 1
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**ETANERCEPT**

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.


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 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. Application 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 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 (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. **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) - balance of first supply
Clinical criteria:
The treatment must be as systemic monotherapy; OR
The treatment must be in combination with methotrexate, AND
Patient must have received insufficient therapy under the Initial treatment (whole body) restriction for severe chronic plaque psoriasis to complete 16 weeks treatment; OR
Patient must have received insufficient therapy under the Re-treatment (whole body) restriction for severe chronic plaque psoriasis to complete 16 weeks treatment, AND
The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Treatment criteria:
Must be treated by a dermatologist.

Authority required
TREATMENT OF PATIENTS UNDER 18 YEARS WITH SEVERE CHRONIC PLACED 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 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-
atanercept 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.

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.

Applications for an extension of treatment should 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.

**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 (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

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 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

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.

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.

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.

**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:
     1. 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
     2. 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:
       1. all subscores are rated moderate to severe or 2 of the three subscores are rated severe to very severe; or
       2. 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. Application for approval for completion of a course
   - Applications for a further 8 weeks of treatment to allow for completion of 24 weeks of therapy should be submitted with a PASI assessment.
   - The PASI assessment must be conducted after at least 12 weeks of treatment.
   - This assessment must be submitted to Department of Human Services (the Department) within 1 month of the completion of 12 weeks of treatment. Where a response assessment is not undertaken and submitted to the Department within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department on 1800 700 270 to discuss.
4. Baseline measurements to determine response.
   - The Department will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for etanercept. However, prescribers may provide new baseline measurements any time that an initial or re-treatment authority is submitted and subsequent response will be assessed according to this revised PASI score.
   - To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of gaining approval for the remainder of 24 weeks treatment.
5. Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.
   - A patient who wishes to start a second or subsequent treatment course with etanercept following a break in PBS-subsidised etanercept therapy of at least 12 months must requalify for treatment under the initial treatment restriction. The most recent PASI assessment must be no more than 1 month old at the time of application.
   - Severe chronic plaque psoriasis
   - Treatment Phase: Re-treatment (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 retreatment 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
HOBART TAS 7001
No increase in the maximum quantity or number of units may be authorised.
No increase in the maximum number of repeats may be authorised.
Special Pricing Arrangements apply.

**ETANERCEPT Injection 50 mg in 1 mL single use auto-injector, 4, 1**

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**ETANERCEPT Injections 50 mg in 1 mL single use pre-filled syringes, 4, 1**

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

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**GOLIMUMAB**

**Authority required**
Severe active rheumatoid arthritis
Treatment Phase: Continuing treatment

Clinical criteria:
Patient must have a documented history of severe active rheumatoid arthritis, AND
Patient must have demonstrated an adequate response to treatment with this drug, AND
Patient must have received this drug as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment, AND
Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction, AND
The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

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

**Treatment criteria:**
Must be treated by a rheumatologist; OR
Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab or tocilizumab.

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 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 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).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:
(1) a completed authority prescription form and
(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

All applications for continuing treatment with golimumab must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 12 weeks of treatment with a PBS subsidised bDMARD while they continue to show a sufficient response to treatment with the PBS subsidised bDMARD.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with golimumab.

If a patient fails to demonstrate a response to treatment with golimumab under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**Note**
Special Pricing Arrangements apply.

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

Prescribing information (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 SEVERE ACTIVE RHEUMATOID ARTHRITIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab) and the T-cell co-stimulation modulator (abatacept).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any one time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:
- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy;
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who...
has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or

(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or

(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or

(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab and tocilizumab, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:

Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient’s weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:

A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept patients:

Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.
In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements. To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing

DMARD therapy.

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Continuing Treatment – balance of supply

Clinical criteria:

Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, AND

The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

Treatment criteria:

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

golimumab 50 mg/0.5 mL injection, 1 x 0.5 mL syringe

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golimumab 50 mg/0.5 mL injection, 1 x 0.5 mL syringe

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**GOLIMUMAB**

Authority required

Ankylosing spondylitis

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have a documented history of active ankylosing spondylitis, AND
Patient must have received this drug as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment in this treatment cycle, AND
Patient must have demonstrated an adequate response to treatment with this drug.

Population criteria:
Patient must be an adult.

Treatment criteria:
Must be treated by a rheumatologist.
An adequate response is defined as an improvement from baseline of at least 2 of the BASDAI and 1 of the following:
(a) an ESR measurement no greater than 25 mm per hour; or
(b) a CRP measurement no greater than 10 mg per L; or
(c) an ESR or CRP measurement reduced by at least 20% from baseline.
Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and supplied in all subsequent continuing treatment applications.
The authority application must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form.
All measurements provided must be no more than 1 month old at the time of application.
A maximum of 24 weeks of treatment with this drug will be authorised under this criterion.
All applications for continuing treatment with this drug must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment following an initial treatment course it must be made following a minimum of 12 weeks of treatment with this drug. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.
Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised bDMARD was approved in this cycle and the date of the first application under a new cycle.

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

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

Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:

Department of Human Services

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**ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS**

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GOLIMUMAB

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months)

Clinical criteria:

Patient must have severe active rheumatoid arthritis, AND
Patient must have received no PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition in the previous 24 months, AND
Patient must not have failed previous PBS-subsidised treatment with this drug for this condition, and have not already failed, or ceased to respond to, PBS-subsidised bDMARD treatment for this condition 5 times, AND
Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR
Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR
Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above, must include at least 3 months continuous treatment with each of at least 2 DMARDs, with one or more of the following DMARDs being used in place of the DMARDs which are contraindicated or not tolerated: (i) azathioprine at a dose of at least 1 mg/kg per day; and/or (ii) cyclosporin at a dose of at least 2 mg/kg/day; and/or (iii) sodium aurothiomalate at a dose of 50 mg weekly, AND
Patient must not receive more than 16 weeks of treatment under this restriction, AND
The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a rheumatologist; OR
Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab or tocilizumab.

If methotrexate is contraindicated according to the TGA-approved Product Information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances.

The requirement to triall at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance and dose for each DMARD must be provided in the authority application.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and
(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form; and
(3) a signed patient acknowledgement.

Assessment of a patient's response to an initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility
for continuing treatment, must be submitted no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

Applications for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

- an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either
  - (a) a total active joint count of at least 20 active (swollen and tender) joints; or
  - (b) at least 4 active joints from the following list of major joints:
    - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
    - (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Where the baseline joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP is provided with the initial application, the same marker will be used to determine response.

Note
The Department of Human Services website (www.humanservices.gov.au) has details of the toxicities, including severity, which will be accepted for the following purposes:

- (a) exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose;
- (b) substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial;
- (c) exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy.

**Authority required**
Severe active rheumatoid arthritis
Treatment Phase: Initial treatment - Initial 2 (change or re-commencement of treatment after break of less than 24 months)

**Clinical criteria:**
Patient must have a documented history of severe active rheumatoid arthritis, AND
Patient must have received prior PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition and are eligible to receive further bDMARD therapy, AND
Patient must not receive more than 16 weeks of treatment under this restriction, AND

The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

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

**Treatment criteria:**
Must be treated by a rheumatologist; OR
Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab or tocilizumab.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form and
- (b) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

Application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.
If a patient fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:
   (i) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

**Note**

Special Pricing Arrangements apply.

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

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

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826

HOBART TAS 7001

TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab) and the T-cell co-stimulation modulator (abatacept).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:

- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy;
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent course of PBS-subsidised therapy was with rituximab. A patient whose most recent course of PBS-subsidised treatment with a bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonist.

A patient receiving PBS-subsidised treatment with rituximab, the interleukin-6 inhibitor (tocilizumab) and the T-cell co-stimulation modulator (abatacept).
minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks. Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:
Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients, if new baseline measurements are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient’s weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:
A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug provided they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients:
A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept patients:
Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD.

However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.
Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months) or Initial 2 (change or recommencement of treatment after break of less than 24 months) – balance of supply.

**Clinical criteria:**

Patient must have received insufficient therapy with this drug under the Initial 1 (new patient or patient recommencing treatment after break of more than 24 months) restriction to complete 16 weeks treatment; OR

Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement of treatment after break of less than 24 months) restriction to complete 16 weeks treatment. **AND**

The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Treatment criteria:**

Must be treated by a rheumatologist; **OR**

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Note**

Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

### golimumab 50 mg/0.5 mL injection, 1 x 0.5 mL syringe

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**GOLIMUMAB**

**Authority required**

Severe psoriatic arthritis

Treatment Phase: Continuing treatment

**Clinical criteria:**

Patient must have a documented history of severe active psoriatic arthritis, **AND**

Patient must have received this drug as their most recent course of PBS-subsidised treatment with a biological agent for this condition in the current Treatment Cycle, **AND**

Patient must demonstrate, at the time of application, an adequate response to treatment with this drug, **AND**

Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

**Population criteria:**

Patient must be an adult.

**Treatment criteria:**

Must be treated by a rheumatologist; **OR**

Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab or infliximab.

An adequate response to treatment is defined as:

- an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and
- either of the following:
  - (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
  - (b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:
    - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
    - (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications.
All applications for continuing treatment with this drug must include a measurement of response to the most recent course of PBS-subsidised therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with the initial treatment course.

Where a response assessment is not submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

Note

Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

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

Prescribing information (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 SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, certolizumab pegol, etanercept, golimumab and infliximab for adult patients with severe active psoriatic arthritis.

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological agents at any 1 time.

Where the term 'biological agents' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab and infliximab only.

Patients receiving PBS-subsidised treatment for psoriatic arthritis are able to commence a ' Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they maintain 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 ceased or failed to sustain a response to treatment 3 times, they are deemed to have completed a single Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological therapy before they are eligible to commence another Cycle (further details are under ‘(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy’ below).

The duration of the break in therapy will be measured from the date of 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 may change to an alternate agent which they have not previously failed, if they wish to continue PBS-subsidised biological treatment.

Patients for whom a break in PBS-subsidised therapy of less than 5 years has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle. There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe active psoriatic arthritis.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); and

(ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; and

(iii) patients wish to re-commence treatment with a specific biological agent following a break in PBS-subsidised therapy with that specific agent (Initial 2).

All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept and golimumab, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), and 22 weeks of therapy for infliximab. It is recommended that patients be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological agent supply.

Patients must be assessed for response to any course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

Grandfather patients - certolizumab pegol only.

For patients who commenced treatment with certolizumab pegol for psoriatic arthritis prior to 1 April 2015, applications for
initial PBS-subsidized treatment as continuing therapy may be made under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with any biological agent prior to PBS listing of that agent.

Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment for all agents. Approval will be based on the criteria included in the relevant restriction.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological agent, patients may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. Patients are eligible to receive continuing biological treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

Patients must be assessed for response to a course of continuing therapy, and the assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

(3) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate biological agent without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements.

Patients may swap to an alternate biological agent at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological agent at the time of the application or not.

Within a Treatment Cycle patients may alternate between therapy with any biological agent of their choice (1 at a time) providing:

- (i) they have not received PBS-subsidised treatment with that particular biological agent previously; or
- (ii) they have demonstrated an adequate response to that particular biological agent if they have previously trialled it on the PBS; and
- (iii) they have not previously failed to respond to treatment 3 times in this Treatment Cycle.

To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the biological agent the patient is ceasing.

(4) Baseline measurements to determine response

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the indices of disease severity submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response. To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

Patients who wish to trial a second or subsequent treatment Cycle following a break in PBS-subsidised biological therapy of at least 5 years, must re-qualify for initial treatment with respect to both the indices of disease severity. Patients must have received treatment with methotrexate and sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured.

**Authority required**

Severe psoriatic arthritis

**Treatment Phase:** Continuing treatment - balance of supply

**Clinical criteria:**

Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, AND

The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Treatment criteria:**

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Note**

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

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

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
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 (BASM); or (iii) limitation of chest expansion relative to normal values for age and gender, AND
Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months.
Population criteria:
Patient must be an adult.
Treatment criteria:
Must be treated by a rheumatologist.
The application must include details of the NSAIDs trialled, their doses and duration of treatment.
If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include a 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
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

Golimumab 50 mg/0.5 mL injection, 1 x 0.5 mL syringe

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HOBART TAS 7001
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

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

Prescribing information (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 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 may remain 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.

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

GOLIMUMAB

Authority required

Severe psoriatic arthritis

Treatment Phase: Initial treatment – Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more)

Clinical criteria:
Patient must have severe active psoriatic arthritis, AND
Patient must have received no prior PBS-subsidised treatment with a biological agent for this condition; OR
Patient must have received no PBS-subsidised treatment with a biological agent for at least 5 years if they have previously received PBS-subsidised treatment with a biological agent for this condition, AND
Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months, AND
Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; OR
Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months, AND
Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:
Patient must be an adult.

Treatment criteria:
Must be treated by a rheumatologist; OR
Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.
For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab or infliximab.
Where treatment with methotrexate, sulfasalazine or leflunomide is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.
Where intolerance to treatment with methotrexate, sulfasalazine or leflunomide developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.
The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:
an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; and either
(a) an active joint count of at least 20 active (swollen and tender) joints; or
(b) at least 4 active joints from the following list of major joints:
(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).
If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.
The authority application must be made in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form; and
(3) a signed patient acknowledgement.

Note
Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 3 months treatment with methotrexate and 3 months treatment with sulfasalazine or leflunomide can be found on the Department of Human Services website (www.humanservices.gov.au)

**Authority required**
Severe psoriatic arthritis
Treatment Phase: Initial treatment – Initial 2 (change or recommencement of treatment)

**Clinical criteria:**
Patient must have a documented history of severe active psoriatic arthritis, **AND**
Patient must have received prior PBS-subsidised treatment with a biological agent for this condition within this Treatment Cycle, **AND**
Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological agents within this Treatment Cycle, **AND**
Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug during the current Treatment Cycle, **AND**
Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**
Patient must be an adult.

**Treatment criteria:**
Must be treated by a rheumatologist; OR
Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.
For the purposes of this restriction ‘biological agent’ means adalimumab, certolizumab pegol, etanercept, golimumab or infliximab.
The authority application must be made in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form.
Applications for a patient who has previously received PBS-subsidised treatment with this drug within this Treatment Cycle who wishes to recommence therapy with this drug within this same Cycle, must be accompanied by evidence of a response to the patient’s most recent course of PBS-subsidised treatment with this drug.
Where the most recent course of PBS-subsidised treatment was approved under either of the initial treatment restrictions (i.e. for patients with no prior PBS-subsidised biological therapy or, under this restriction, for patients who have received previous PBS-subsidised biological therapy), the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must have been submitted no later than 4 weeks from the date that course was ceased.
Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment submitted no later than 4 weeks from the date that course was ceased.
Where a response assessment was not submitted within these timeframes, the patient will be deemed to have failed to respond to treatment.
An adequate response to treatment is defined as:
an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and
either of the following:
(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:
(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

**Note**
The assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted to the Department of Human Services no later than 4 weeks from the cessation of the treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.
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 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.
Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (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 SEVERE ACTIVE PSORIATIC ARTHRITIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, certolizumab pegol, etanercept, golimumab and infliximab for adult patients with severe active psoriatic arthritis.

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological agents at any 1 time. Where the term 'biological agents' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab and infliximab only.

Patients receiving PBS-subsidised treatment for psoriatic arthritis are able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

Following demonstration of response to initial treatment, these biological agents are available under the PBS for continuing treatment as set out in the continuing treatment restriction for each agent. Once patients have either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological therapy before they are eligible to commence another Cycle [further details are under '(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' below].

The duration of the break in therapy will be measured from the date the last approval for PBS-subsidised treatment was granted in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Cycle.

Within the same Cycle, patients are not allowed to fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for any biological agent, they must change to an alternate agent which they have not previously failed, if they wish to continue PBS-subsidised biological treatment.

Patients for whom a break in PBS-subsidised therapy of less than 5 years has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle. There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe active psoriatic arthritis.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); and

(ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; and

(iii) patients wish to re-commence treatment with a specific biological agent following a break in PBS-subsidised therapy with that specific agent (Initial 2).

All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept and golimumab, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), and 22 weeks of therapy for infliximab. It is recommended that patients be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological agent supply.

Patients must be assessed for response to any course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

Grandfather patients - certolizumab pegol only.

For patients who commenced treatment with certolizumab pegol for psoriatic arthritis prior to 1 April 2015, applications for initial PBS-subsidised treatment as continuing therapy may be made under the relevant initial treatment restriction (Initial 3).

These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with any biological agent prior to PBS listing of that agent.

Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment for all agents. Approval will be based on the criteria included in the relevant restriction.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological agent, patients may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. Patients are eligible to receive continuing biological treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

Patients must be assessed for response to a course of continuing therapy, and the assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

(3) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate biological agent without having to re-qualify with respect to either the indices of disease severity [i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count] or the prior non-biological therapy requirements.

Patients may swap to an alternate biological agent at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological agent at the time of the application or not.

Within a Treatment Cycle patients may alternate between therapy with any biological agent of their choice (1 at a time) providing:

(i) they have not received PBS-subsidised treatment with that particular biological agent previously; or

(ii) they have demonstrated an adequate response to that particular biological agent if they have previously trialled it on the PBS; and

(iii) they have not previously failed to respond to treatment 3 times in this Treatment Cycle.

To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is
General

important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the biological agent the patient is ceasing.

(4) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the indices of disease severity submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment application is submitted within a treatment Cycle and these revised baseline measurements will be used to assess response.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

Patients who wish to trial a second or subsequent treatment Cycle following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment with respect to both the indices of disease severity. Patients must have received treatment with methotrexate and sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured.

Authority required

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more) or Initial 2 (change or recommencement of treatment) - balance of supply

Clinical criteria:
Patient must have received insufficient therapy with this drug under the Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more) restriction to complete 16 weeks treatment; OR
Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement of treatment) restriction to complete 16 weeks treatment, AND

The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Treatment criteria:
Must be treated by a rheumatologist; OR
Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

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

Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826

HOBART TAS 7001

golimumab 50 mg/0.5 mL injection, 1 x 0.5 mL syringe

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Interleukin inhibitors

USTEKINUMAB

Authority required

Continuing treatment (Whole body)
Continuing PBS-subsidised treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over:
(a) who have a documented history of severe chronic plaque psoriasis; and
(b) whose most recent course of PBS-subsidised biological treatment for this condition in this Treatment Cycle was with ustekinumab; and
(c) who have demonstrated an adequate response to their most recent course of treatment with ustekinumab.

An adequate response to treatment is defined as:
A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the pre-biological treatment baseline value for this Treatment Cycle.

This assessment must be provided to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with ustekinumab, the assessment of response must be after a minimum of 12 weeks of treatment with an initial course.

Applications for authorisation must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) the completed Psoriasis Area and Severity Index (PASI) calculation sheet along with the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 1 month old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with ustekinumab.

A maximum of 24 weeks of treatment with ustekinumab will be authorised under this restriction.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single injection. Up to a maximum of 1 repeat will be authorised.

Where fewer than 1 repeat is requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for continuing authority applications, or for treatment that would otherwise extend the treatment period beyond 24 weeks.

A PASI assessment of the patient's response must be conducted within 4 weeks prior to completion of this course of treatment. This assessment, which will be used to determine eligibility for further continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with ustekinumab. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised ustekinumab treatment.

Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may re-commence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

**Authority required**

Continuing 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 is defined as the plaque or plaques assessed prior to biological treatment showing:
(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the pre-biological treatment baseline values; or
(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the pre-biological treatment baseline value.

This assessment must be provided to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with ustekinumab, the assessment of response must be after a minimum of 12 weeks of treatment with an initial course.

Applications for authorisation must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams along with the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 1 month old at the time of application.

A maximum of 24 weeks of treatment with ustekinumab will be authorised under this restriction.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single injection. Up to a maximum of 1 repeat will be authorised.

Where fewer than 1 repeat is requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for continuing authority applications, or for treatment that would otherwise extend the treatment period beyond 24 weeks.

A PASI assessment of the patient's response must be conducted within 4 weeks prior to completion of this course of treatment. This assessment, which will be used to determine eligibility for further continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to...
have failed to respond to treatment with ustekinumab. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised ustekinumab treatment.

The PASI assessment for continuing treatment must be performed on the same affected area assessed at baseline. Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may re-commence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

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

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe ustekinumab should be forwarded to:
Medicare Australia
Prior Written Approval of Specialised Drugs
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.

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 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 continuing 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.

No applications for increased repeats will be authorised. Special Pricing Arrangements apply.

### USTEKINUMAB

**Authority required**

Initial treatment [Initial 1, Whole body (New patients — No prior biological agent)]

Initial treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over who:

- (a) have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis; and
- (b) have not received any prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle; and
- (c) have signed a patient and prescriber acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment (whole body); and
- (d) have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 3 of the following 4 treatments:
  - (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or
  - (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; and/or
  - (iii) cyclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; and/or
  - (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, please provide details at the time of application. If intolerance to treatment develops during the relevant period of use, which is of a severity to necessitate permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of acceptable...
toxicities including severity, associated with phototherapy, methotrexate, cyclosporin and acitretin, can be found on the Medicare Australia website (www.medicareaustralia.gov.au).

The following initiation criterion indicates failure to achieve an adequate response and must be demonstrated in all patients at the time of the application:

(a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 1 month old at the time of application.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; and

(iii) the signed patient and prescriber acknowledgements.

A maximum of 28 weeks of treatment with ustekinumab will be authorised under this restriction.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single injection. Up to a maximum of 2 repeats will be authorised. Where fewer than 2 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 28 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period beyond 28 weeks.

A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to 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)]

Treatement as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over who:

(a) have a documented history of severe chronic plaque psoriasis; and

(b) have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle; and

(c) have not failed PBS-subsidised therapy with ustekinumab for the treatment of this condition in the current Treatment Cycle.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and

(ii) details of prior biological treatment, including dosage, date and duration of treatment.

Applications for patients who have demonstrated a response to PBS-subsidised ustekinumab treatment within this Treatment Cycle and who wish to re-commence ustekinumab treatment within the same Cycle following a break in therapy, will only be approved where evidence of the patient's response to their most recent course of PBS-subsidised ustekinumab treatment has been submitted to Medicare Australia within 1 month of cessation of treatment.

A maximum of 28 weeks of treatment with ustekinumab will be authorised under this restriction.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single injection. Up to a maximum of 2 repeats will be authorised. Where fewer than 2 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 28 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period beyond 28 weeks.

A PASI assessment of the patient's response to this course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with ustekinumab. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.
It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised ustekinumab treatment.

Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. Those patients may re-commence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

**Authority required**

Initial treatment. [Initial 1, Face, hand, foot (New patients — No prior biological agent)]

Initial treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over who:

(a) have severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis; and

(b) have not received any prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle; and

(c) have signed a patient and prescriber acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment (face, hand, foot); and

(d) have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, at least 3 of the following 4 treatments:

(i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or

(ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; and/or

(iii) cyclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; and/or

(iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity to necessitate permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of acceptable toxicities including severity, associated with phototherapy, methotrexate, cyclosporin and acitretin, can be found on the Medicare Australia website (www.medicareaustralia.gov.au).

The following initiation criterion indicates failure to achieve an adequate response and must be demonstrated in all patients at the time of the application:

(a) Chronic plaque psoriasis 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.

**Authority required**

Initial or re-Treatment [Initial 2, Face, hand, foot (Received prior biological agent under PBS)]

Treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over who:

(a) have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot; and

(b) have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle; and

(c) have not failed PBS-subsidised therapy with ustekinumab for the treatment of this condition in the current Treatment Cycle.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and

(ii) details of prior biological treatment, including dosage, date and duration of treatment.

Applications for patients who have demonstrated a response to PBS-subsidised ustekinumab treatment within this Treatment Cycle and who wish to re-commence ustekinumab treatment within the same Cycle following a break in therapy, will only be approved where evidence of the patient's response to their most recent course of PBS-subsidised ustekinumab treatment has been submitted to Medicare Australia within 1 month of cessation of treatment.

A maximum of 28 weeks of treatment with ustekinumab will be authorised under this restriction.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single injection. Up to a maximum of 2 repeats will be authorised.

Where fewer than 2 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 28 weeks of treatment may be requested by telephone or by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period beyond 28 weeks.

A PASI assessment of the patient's response to this course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with ustekinumab. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised ustekinumab treatment.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may re-commence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised ustekinumab treatment 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.

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 are deemed to have completed their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised ustekinumab treatment.
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).

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.
No applications for increased repeats will be authorised.
Special Pricing Arrangements apply.

### ustekinumab 45 mg/0.5 mL injection, 1 x 0.5 mL vial

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### Calcineurin inhibitors

#### CYCLOSPORIN

**Caution**
Careful monitoring of patients is mandatory.

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#### TACROLIMUS

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Careful monitoring of patients is mandatory.

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**MUSCULO-SKELETAL SYSTEM**

### AZATHIOPRINE

**Note**

Shared Care Model:

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

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### METHOTREXATE

methotrexate 10 mg tablet, 15

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methotrexate 2.5 mg tablet, 30

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### METHOTREXATE

**Restricted benefit**

For patients requiring doses greater than 20 mg per week

methotrexate 10 mg tablet, 50

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### MUSCULO-SKELETAL SYSTEM

#### ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS

**Acetic acid derivatives and related substances**

#### DICLOFENAC

diclofenac sodium 100 mg suppository, 20

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**Restricted benefit**

Chronic arthropathies (including osteoarthritis) with an inflammatory component

**Restricted benefit**

Bone pain due to malignant disease

diclofenac sodium 25 mg tablet: enteric, 50 tablets

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**MUSCULO-SKELETAL SYSTEM**

### diclofenac sodium 25 mg tablet: enteric, 50 tablets

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**diclofenac sodium 50 mg tablet: enteric, 50 tablets**

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### INDOMETHACIN

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#### indomethacin 100 mg suppository, 20

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### INDOMETHACIN

**Restricted benefit**
= Chronic arthropathies (including osteoarthritis) with an inflammatory component

**Restricted benefit**
= Bone pain due to malignant disease

#### indomethacin 25 mg capsule, 50

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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:

- (a) acute pain;
- (b) soft tissue injury;
**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.

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.

---

**PIROXICAM**

**Restricted benefit**
Chronic arthropathies (including osteoarthritis) with an inflammatory component

---

Schedule of Pharmaceutical Benefits 413
### Piroxicam 10 mg capsule, 50
5203W  
<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
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<tbody>
<tr>
<td>1</td>
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<td>12.54</td>
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<td>*Mobilis 10 [AF]</td>
<td>*Terry White Chemists</td>
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### Piroxicam 10 mg tablet: dispersible, 50
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### Piroxicam 10 mg tablet: dispersible, 50
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### Piroxicam 20 mg capsule, 25
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### Piroxicam 20 mg tablet: dispersible, 25
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### Propionic acid derivatives

#### IBUPROFEN

### Ibuprofen 400 mg tablet, 30
3192B  
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<td>10.68</td>
<td>Brufen [GO]</td>
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#### IBUPROFEN

**Restricted benefit**
- Chronic arthropathies (including osteoarthritis) with an inflammatory component
- Bone pain due to malignant disease

### Ibuprofen 400 mg tablet, 30
3190X  
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<tr>
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### Ibuprofen 400 mg tablet, 30
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<tr>
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## KEToprofen

**Ketoprofen 100 mg suppository, 20**

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<td>Orudis [SW]</td>
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**Ketoprofen 100 mg suppository, 20**

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### Restricted Benefit

Chronic arthropathies (including osteoarthritis) with an inflammatory component

**Ketoprofen 200 mg capsule: modified release, 28 capsules**

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**Ketoprofen 200 mg capsule: modified release, 28 capsules**

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## NAProxen

**Naproxen 1 g tablet: modified release, 28**

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**Naproxen 1 g tablet: modified release, 28**

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**Naproxen 250 mg tablet, 50**

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<td>*Inza 250 [AF]</td>
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**Naproxen 250 mg tablet, 50**

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<td>*Inza 250 [AF]</td>
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**Naproxen 500 mg tablet, 50**

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**Naproxen 500 mg tablet, 50**

<table>
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**Naproxen 750 mg tablet: modified release, 28 tablets**

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**Naproxen 750 mg tablet: modified release, 28 tablets**

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<td>12.42</td>
<td>13.57</td>
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</table>
General

**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.

**Naproxen 125 mg/5 mL oral liquid, 474 mL**

1658G

<table>
<thead>
<tr>
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<th>No. of Rpts</th>
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**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.

**Naproxen sodium 550 mg tablet, 50**

1795L

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**Naproxen sodium 550 mg tablet, 50**

5186Y

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**Fenamates**

**MEFENAMIC ACID**

*Restricted benefit*

Dysmenorrhoea

*Restricted benefit*

Menorrhagia

mefenamic acid 250 mg capsule, 50

1824B

<table>
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<td>18.50</td>
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<td>Ponstan [PF]</td>
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</tbody>
</table>

**Coxibs**

**CELECOXIB**

*Restricted benefit*

Osteoarthritis

**Clinical criteria:**
- The treatment must be for symptomatic treatment.

*Restricted benefit*

Rheumatoid arthritis

**Clinical criteria:**
- The treatment must be for symptomatic treatment.

*Note*

The use of this drug 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.
celecoxib 100 mg capsule, 60

<table>
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<td>* Celaxib [AF]</td>
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<td>* Celecoxib Actavis [GN]</td>
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<td>* Celecoxib GH [GQ]</td>
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<td>* Terry White Chemists</td>
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<td>* Celebrex [PF]</td>
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celecoxib 200 mg capsule, 30

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<td>* Celebrex [PF]</td>
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<td>* Celecoxib RBX [RA]</td>
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<td>* Celexi [QA]</td>
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<td>* Kudeq [FZ]</td>
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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.

hydroxychloroquine sulfate 200 mg tablet, 100

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
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<tr>
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<td>* Hydroxychloroquine Actavis [GN]</td>
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<td>* Plaquenil [SW]</td>
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<td>Chem mart Hydroxychloroquine [CH]</td>
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Gold preparations

AURANOFIN

Caution
Regular blood and urine checks are essential.

AURANOFIN Capsule 3 mg, 60

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<td>37.70</td>
<td>Ridaura [GH]</td>
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</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.

auranofin 3 mg tablet, 60

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AUROTHIOMALATE SODIUM

Caution
Regular blood and urine checks are essential.
MUSCULO-SKELETAL SYSTEM

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.

aurothiomalate sodium 10 mg/0.5 mL injection, 10 x 0.5 mL ampoules

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<td>Myocrisin [SW]</td>
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aurothiomalate sodium 20 mg/0.5 mL injection, 10 x 0.5 mL ampoules

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<td>Myocrisin [SW]</td>
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aurothiomalate sodium 50 mg/0.5 mL injection, 10 x 0.5 mL ampoules

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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.

penicillamine 125 mg tablet, 100

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penicillamine 250 mg tablet, 100

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<td>D-Penamine [AL]</td>
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**MUSCLE RELAXANTS**

**MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS**

Other centrally acting agents

**BACLOFEN**

baclofen 10 mg tablet, 100

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<thead>
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baclofen 25 mg tablet, 100

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**DANTROLENE**

Restricted benefit
Treatment of chronic spasticity

dantrolene sodium 25 mg capsule, 100

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<td>Dantrium [PF]</td>
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## ANTI-RHEUMATOID AGENTS

### MUSCULO-SKELETAL SYSTEM

### Schedule of Pharmaceutical Benefits

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<tr>
<th>sunny.doe.corporation.com</th>
<th>general.doe.corporation.gov</th>
<th>public.doe.corporation.gov</th>
<th>personal.doe.corporation.gov</th>
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</thead>
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### ANTIGOUT PREPARATIONS

#### Preparations inhibiting uric acid production

**ALLOPURINOL**

**Note**
The dose should be adjusted in accordance with renal function.

**Baseline uricosuric therapy**

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**ALLOPURINOL**

**Note**
The dose should be adjusted in accordance with renal function.

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<tr>
<th>allopurinol 300 mg tablet, 60</th>
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**ALLOPURINOL**

**Note**
The dose should be adjusted in accordance with renal function.

<table>
<thead>
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<th>allopurinol 100 mg tablet, 100</th>
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<td>Max Qty Packs</td>
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<td>2</td>
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**allopurinol 100 mg tablet, 200**

| **2600W**                     |
| Max Qty Packs | No. of Rpts | Premium ($) | DPMQ ($)  | MRVSN ($) | Brand Name and Manufacturer |
| 1                | 2           | ..          | 11.31     | 12.46     | * Allopurinol Sandoz [SZ]   |
|                  |             |             |           |           | * APO-Allopurinol [TX]      |
|                  |             |             |           |           | * GenRx Allopurinol [GX]    |
|                  |             |             |           |           | * Terry White Chemists      |
|                  |             |             |           |           | Allopurinol [TW]            |
|                  |             | ..          | 15.30     | 12.46     | * Zyloprim [QA]             |

**Preparations increasing uric acid excretion**

**PROBENECID**

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<th>probenecid 500 mg tablet, 100</th>
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**COLCHICINE**

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**DRUGS FOR TREATMENT OF BONE DISEASES**

#### DRUGS AFFECTING BONE STRUCTURE AND MINERALIZATION

**Bisphosphonates**

**ALENDRONATE**

**Restricted benefit**

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.

**Restricted benefit**

**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.

**Note**
Anti-resorptive agents in osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride, strontium ranelate and zoledronic acid.

**Restricted benefit**

**Established osteoporosis**

**Clinical criteria:**
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.

<table>
<thead>
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<th>alendronate 70 mg tablet, 4</th>
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<td></td>
<td>* Alendronate-GA [GN]</td>
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<td>* Alendro Once Weekly [QA]</td>
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<td>* Fonat [AL]</td>
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<td></td>
<td>* Terry White Chemists Alendronate 70mg [TW]</td>
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<td></td>
<td>* Alendronate AN [EA]</td>
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<td>* Alendronate Sandoz [SZ]</td>
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<td></td>
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<td>* APO-Alendronate [TX]</td>
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<td>* Densate 70 [DO]</td>
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<td>* Ossmax 70mg [RA]</td>
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</table>

**CLODRONATE**

**Restricted benefit**

Hypercalcaemia of malignancy

**Clinical criteria:**
Patient must have a malignancy refractory to anti-neoplastic therapy.

**Restricted benefit**

Multiple myeloma

**Restricted benefit**

Bone metastases

**Clinical criteria:**
The condition must be due to 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.

<table>
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<td>37.70</td>
<td>Bonefos [BN]</td>
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<td>Bonefos 800 mg [BN]</td>
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</table>
**IBANDRONIC ACID**

**Restricted benefit**
Bone metastases

**Clinical criteria:**
The condition must be due to 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.

Ibandronic acid 50 mg tablet, 28

<table>
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**PAMIDRONATE DISODIUM**

**Restricted benefit**
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.

Pamidronate disodium 15 mg/5 mL injection, 1 x 5 mL vial

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<td>8461H</td>
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<td>*87.96</td>
<td>37.70</td>
<td>Pamisol [HH]</td>
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</table>

Pamidronate disodium 60 mg/10 mL injection, 1 x 10 mL vial

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<td>87.95</td>
<td>37.70</td>
<td>Pamisol [HH]</td>
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</table>

**PAMIDRONATE DISODIUM**

**Restricted benefit**
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.

**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.

Pamidronate disodium 30 mg injection [2 x 30 mg vials] (&) inert substance diluent [2 x 10 mL ampoules], 1 pack

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<tr>
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<td>* Aredia 30 mg [NV]</td>
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Pamidronate disodium 30 mg/10 mL injection, 1 x 10 mL vial

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<td></td>
<td>*87.96</td>
<td>37.70</td>
<td>* Pamisol [HH]</td>
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**RISEDRONATE**

**Restricted benefit**
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.
RISEDRONATE

Restricted benefit
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.

Restricted benefit
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.

Note
Anti-resorptive agents in osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride, strontium ranelate and zoledronic acid.

RISEDRONATE SODIUM Tablet 35 mg (enteric coated), 4

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risedronate sodium 150 mg tablet, 1

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risedronate sodium 5 mg tablet, 28

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TILDUDRONATE

Restricted benefit
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.

**tiludronate 200 mg tablet, 56**

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**ZOLEDRONIC ACID**

*Authority required (STREAMLINED)*

**4876**
Symptomatic Paget disease of bone
Only 1 treatment each year per patient will be PBS-subsidised

**zoledronic acid 5 mg/100 mL injection, 1 x 100 mL vial**

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**ZOLEDRONIC ACID**

*Authority required (STREAMLINED)*

**4100**
Corticosteroid-induced osteoporosis

**Clinical criteria:**
Patient must currently be on long-term (at least 3 months), high-dose (at least 7.5 mg per day prednisolone or equivalent) corticosteroid therapy, **AND**
Patient must have a Bone Mineral Density (BMD) T-score of -1.5 or less, **AND**
Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition, **AND**
Patient must not receive more than one PBS-subsidised treatment per year.

The duration and dose of corticosteroid therapy together with the date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

*Authority required (STREAMLINED)*

**4149**
Osteoporosis

**Clinical criteria:**
Patient must have a Bone Mineral Density (BMD) T-score of -3.0 or less, **AND**
Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition, **AND**
Patient must not receive more than one PBS-subsidised treatment per year.

**Population criteria:**
Patient must be aged 70 years or older.

The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

*Authority required (STREAMLINED)*

**4157**
Established osteoporosis

**Clinical criteria:**
Patient must have fracture due to minimal trauma, **AND**
Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition, **AND**
Patient must not receive more than one PBS-subsidised treatment per year.

The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

**Note**
Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride, strontium ranelate and zoledronic acid.

**zoledronic acid 5 mg/100 mL injection, 1 x 100 mL vial**

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**Bisphosphonates, combinations**

**ALENDRONATE + COLECALCIFEROL**

*Authority required (STREAMLINED)*

**4122**
Corticosteroid-induced osteoporosis

Clinical criteria:
Patient must currently be on long-term (at least 3 months), high-dose (at least 7.5 mg per day prednisolone or equivalent) corticosteroid therapy, AND
Patient must have a Bone Mineral Density (BMD) T-score of -1.5 or less, AND Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.
The duration and dose of corticosteroid therapy together with the date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

Authority required (STREAMLINED)

4133
Osteoporosis

Clinical criteria:
Patient must have a Bone Mineral Density (BMD) T-score of -2.5 or less, AND Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

Population criteria:
Patient must be aged 70 years or older.
The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

Authority required (STREAMLINED)

4123
Established osteoporosis

Clinical criteria:
Patient must have fracture due to minimal trauma, AND Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.
The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated.
A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

Note
Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride, strontium ranelate and zoledronic acid.

### alendronate 70 mg + colecaltifero 140 microgram tablet, 4

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### ALENDRONATE + COLECALTIFERO

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.

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.

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### ALENDRONATE + COLECALCIFEROL (&) CALCIUM CARBONATE

**Authority required (STREAMLINED)**

#### 4122
Corticosteroid-induced osteoporosis

**Clinical criteria:**
- Patient must currently be on long-term (at least 3 months), high-dose (at least 7.5 mg per day prednisolone or equivalent) corticosteroid therapy, **AND**
- Patient must have a Bone Mineral Density (BMD) T-score of -1.5 or less, **AND**
- 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.

---

### alendronate 70 mg + coleccalciferol 70 microgram tablet, 4 pack

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- Alendronate D3 70 mg/70 microgram [UA]
- APO-Alendronate Plus D3 70 mg/70 mcg [TX]
- Fosamax Plus [MK]

### alendronate 70 mg + coleccalciferol 140 microgram tablet [4] (&) calcium (as carbonate) 500 mg tablet [48], 1 pack

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- Alendronate Plus D3 and Calcium Sandoz [SZ]
- Dronalen Plus D-Cal [FR]
- ReddyMax Plus D-Cal [RZ]
- Alendronate Plus D3 Calcium Actavis [UA]
- Fosamax Plus D-Cal [MK]
**RISEDRONATE (&) 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.

**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.

**Note**

Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride, strontium ranelate and zoledronic acid.

**RISEDRONATE SODIUM and CALCIUM CARBONATE** Pack containing 4 enteric coated tablets risedronate sodium 35 mg and 24 tablets calcium carbonate 1.25 g (equivalent to 500 mg calcium), 1

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risedronate sodium 35 mg tablet [4] (&) calcium (as carbonate) 500 mg tablet [24], 28

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**RISEDRONATE (&) CALCIUM CARBONATE + COLECALCIFEROL**

**Authority required (STREAMLINED)**

**4122**

Corticosteroid-induced osteoporosis

**Clinical criteria:**
- Patient must currently be on long-term (at least 3 months), high-dose (at least 7.5 mg per day prednisolone or equivalent) corticosteroid therapy, **AND**
- Patient must have a Bone Mineral Density (BMD) T-score of -1.5 or less, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The duration and dose of corticosteroid therapy together with the date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

**Authority required (STREAMLINED)**

**4133**

Osteoporosis

**Clinical criteria:**
- Patient must have a Bone Mineral Density (BMD) T-score of -2.5 or less, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

**Population criteria:**
- Patient must be aged 70 years or older.

The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.
Established osteoporosis

Clinical criteria:
- Patient must have fracture due to minimal trauma, AND
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.
- The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated.
- A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

Note
- Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride, strontium ranelate and zoledronic acid.

RISEDRONATE SODIUM and CALCIUM CARBONATE 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

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Other drugs affecting bone structure and mineralization

- **CALCITRIOL**
  - Authority required (STREAMLINED)
    - 1165 Hypocalcaemia due to renal disease
  - Authority required (STREAMLINED)
    - 1166 Hypoparathyroidism
  - Authority required (STREAMLINED)
    - 1167 Hypophosphataemic rickets
  - Authority required (STREAMLINED)
    - 1467 Vitamin D-resistant rickets
  - Authority required (STREAMLINED)
    - 2636 Treatment for established osteoporosis in patients with fracture due to minimal trauma. The fracture must have been demonstrated radiologically and the year of plain x-ray or CT-scan or MRI scan must be documented in the patient's medical records when treatment is initiated.
    - A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

calcitriol 0.25 microgram capsule, 100

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- **DENOSUMAB**
  - Authority required (STREAMLINED)
    - 4504 Giant cell tumour of bone
  - Clinical criteria:
    - Patient must be one in whom surgical resection is not feasible; OR
    - Patient must be one in whom surgical resection is possible but surgery would result in significant morbidity.
  - Population criteria:
    - Patient must be an adult; OR
    - Patient must be a skeletally mature adolescent.
  - Note
    - Denosumab is not PBS-subsidised for use in patients who have undergone curative surgical resection.

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.
DENOSUMAB

**Authority required (STREAMLINED)**

**Clinical criteria:**
The condition must be due to breast cancer.

**Clinical criteria:**
The condition must be due to castration-resistant prostate 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.

---

**RALOXIFENE**

**Authority required (STREAMLINED)**

**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.

### raloxifene hydrochloride 60 mg tablet, 28

<table>
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<tr>
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### STRONTIUM

**Authority required**
Severe established osteoporosis

**Clinical criteria:**
- Patient must have fracture due to minimal trauma, **AND**
- Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition, **AND**
- Patient must be at high risk of fracture, **AND**
- Patient must be unable to use other medications for the treatment of osteoporosis due to contraindications or intolerance.

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

**Note**
Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride, strontium ranelate and zoledronic acid.

### strontium ranelate 2 g granules, 28 x 2 g sachets

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### TERIPARATIDE

**Authority required**
Severe established osteoporosis

**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.

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.
No increase in the maximum quantity or number of units may be authorised.
No increase in the maximum number of repeats may be authorised.
Special Pricing Arrangements apply.

Teriparatide 20 microgram/dose injection, 1 x 2.4 mL cartridge

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**NERVOUS SYSTEM**

**ANALGESICS**

**OPIOIDS**

*Natural opium alkaloids*

**CODEINE**

codeine phosphate 30 mg tablet, 20

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**CODEINE**

Note
Prescribing of drugs of addiction by dentists is not permitted in some States/Territories.

codeine phosphate 30 mg tablet, 20

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**HYDROMORPHONE**

Caution
The risk of drug dependence is high.

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

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Hydromorphone hydrochloride 2 mg/mL injection, 5 x 1 mL ampoules

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Hydromorphone hydrochloride 50 mg/5 mL injection, 5 x 5 mL ampoules

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Hydromorphone hydrochloride 500 mg/50 mL injection, 1 x 50 mL vial

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**HYDROMORPHONE**

**Caution**
The risk of drug dependence is high.

**Restricted benefit**
Severe disabling pain

**Clinical criteria:**
The condition must be unresponsive to non-narcotic analgesics.

**Note**
Prescribing of drugs of addiction by dentists is not permitted in some States/Territories.

---

**hydromorphone hydrochloride 1 mg/mL oral liquid, 473 mL**

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**hydromorphone hydrochloride 2 mg tablet, 20**

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**hydromorphone hydrochloride 4 mg tablet, 20**

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**hydromorphone hydrochloride 8 mg tablet, 20**

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**HYDROMORPHONE**

**Caution**
The risk of drug dependence is high.

**Restricted benefit**
Severe disabling pain

**Clinical criteria:**
The condition must be unresponsive to non-narcotic analgesics.

**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.

**hydromorphone hydrochloride 1 mg/mL oral liquid, 473 mL**

<table>
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**hydromorphone hydrochloride 4 mg tablet, 20**

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**HYDROMORPHONE**

**Caution**
The risk of drug dependence is high.
General

The risk of drug dependence is high.

**Restricted benefit**

Chronic severe disabling pain

**Clinical criteria:**
The condition must be unresponsive to non-narcotic analgesics.

**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**

**Caution**
The risk of drug dependence is high.

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

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<th>Max Qty Packs</th>
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**morphine sulfate 15 mg/mL injection, 5 x 1 mL ampoules**

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

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**morphine tartrate 120 mg/1.5 mL injection, 5 x 1.5 mL ampoules**

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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.
**NERVOUS SYSTEM**

**Schedule of Pharmaceutical Benefits**

**MORPHINE**

- **Caution**
  The risk of drug dependence is high.

- **Authority required**
  Chronic severe disabling pain

- **Clinical criteria:**
  The condition must be due to cancer, **AND**
  The condition must be unresponsive to non-narcotic analgesics.

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

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

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

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**morphine sulfate 200 mg granules: modified release, 28 sachets**

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**MORPHINE**

- **Caution**
  The risk of drug dependence is high.

- **Restricted benefit**
  Severe disabling pain

- **Clinical criteria:**
  The condition must be due to cancer, **AND**
  The condition must be unresponsive to non-narcotic analgesics.

**morphine sulfate 10 mg tablet, 20**

<table>
<thead>
<tr>
<th></th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMO $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>8669G</td>
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<td>14.66</td>
<td>15.81</td>
<td>Sevredol [MF]</td>
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</table>

**morphine sulfate 20 mg tablet, 20**

<table>
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<th>Premium $</th>
<th>DPMO $</th>
<th>MRVSN $</th>
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</thead>
<tbody>
<tr>
<td>8670H</td>
<td>1</td>
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<td>15.60</td>
<td>16.75</td>
<td>Sevredol [MF]</td>
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</tr>
</tbody>
</table>

**MORPHINE**

- **Caution**
  The risk of drug dependence is high.

- **Restricted benefit**
  Severe disabling pain

- **Clinical criteria:**
  The condition must be unresponsive to non-narcotic analgesics.

**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.

### MORPHINE

**Caution**
The risk of drug dependence is high.

**Restricted benefit**
Chronic severe disabling pain

**Clinical criteria:**
The condition must be unresponsive to non-narcotic analgesics.

**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 hydrochloride 10 mg/mL oral liquid, 200 mL

<table>
<thead>
<tr>
<th>Product Code</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>2124T</td>
<td></td>
<td></td>
<td>27.20</td>
<td>28.35</td>
<td>Ordine 10 [MF]</td>
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</tbody>
</table>

### morphine hydrochloride 2 mg/mL oral liquid, 200 mL

<table>
<thead>
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<th>Product Code</th>
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<th>No. of Rpts</th>
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<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>2122Q</td>
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<td>20.67</td>
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</table>

### morphine hydrochloride 5 mg/mL oral liquid, 200 mL

<table>
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<th>No. of Rpts</th>
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<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tr>
<td>2123R</td>
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<td>23.07</td>
<td>24.22</td>
<td>Ordine 5 [MF]</td>
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</table>

### morphine sulfate 30 mg tablet, 20

<table>
<thead>
<tr>
<th>Product Code</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
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<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
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<td>14.37</td>
<td>15.52</td>
<td>Anamorph [FM]</td>
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</table>

### morphine Capsule 10 mg (containing sustained release pellets), 28

<table>
<thead>
<tr>
<th>Product Code</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>8349K</td>
<td></td>
<td></td>
<td>20.37</td>
<td>21.52</td>
<td>Kapanol [YN]</td>
<td></td>
</tr>
</tbody>
</table>

### morphine Capsule 100 mg (containing sustained release pellets), 28

<table>
<thead>
<tr>
<th>Product Code</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>2841M</td>
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<td></td>
<td>70.81</td>
<td>37.70</td>
<td>Kapanol [YN]</td>
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</tr>
</tbody>
</table>

### morphine Capsule 20 mg (containing sustained release pellets), 28

<table>
<thead>
<tr>
<th>Product Code</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>2839K</td>
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<td>25.35</td>
<td>26.50</td>
<td>Kapanol [YN]</td>
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</table>

### morphine Capsule 50 mg (containing sustained release pellets), 28

<table>
<thead>
<tr>
<th>Product Code</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>2840L</td>
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<td>43.65</td>
<td>37.70</td>
<td>Kapanol [YN]</td>
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</table>

### morphine Sachet containing controlled release granules for oral suspension, 30 mg per sachet, 28

<table>
<thead>
<tr>
<th>Product Code</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
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</thead>
<tbody>
<tr>
<td>8146R</td>
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<td>62.41</td>
<td>37.70</td>
<td>MS Contin Suspension 30 mg [MF]</td>
<td></td>
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</tbody>
</table>

### morphine Sachet containing controlled release granules for oral suspension, 60 mg per sachet, 28

<table>
<thead>
<tr>
<th>Product Code</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
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<tbody>
<tr>
<td>8305D</td>
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<td></td>
<td>70.21</td>
<td>37.70</td>
<td>MS Contin Suspension 60 mg [MF]</td>
<td></td>
</tr>
</tbody>
</table>
### Morphine

**Caution**
The risk of drug dependence is high.

**Restricted benefit**
Severe disabling pain

**Clinical criteria:**
The condition must be unresponsive to non-narcotic analgesics.

**Note**
Prescribing of drugs of addiction by dentists is not permitted in some States/Territories.

#### Morphine Sulfate 10 mg Tablet: Modified Release, 28 Tablets

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>..</td>
<td>..</td>
<td>20.38</td>
<td>21.53</td>
<td>* Momex SR 10 [QA]</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* MORPHINE MR APOTEX [TX]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* MS Contin [MF]</td>
</tr>
</tbody>
</table>

#### Morphine Sulfate 100 mg Granules: Modified Release, 28 Sachets

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>..</td>
<td>..</td>
<td>86.71</td>
<td>37.70</td>
<td>MS Contin Suspension 100 mg</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>[MF]</td>
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</table>

#### Morphine Sulfate 100 mg Tablet: Modified Release, 28 Tablets

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
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<tbody>
<tr>
<td>1</td>
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<td>72.85</td>
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<td>* APOTEX-MORPHINE MR [TX]</td>
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<td></td>
<td></td>
<td>* Momex SR 10 [QA]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* MS Contin [MF]</td>
</tr>
</tbody>
</table>

#### Morphine Sulfate 120 mg Capsule: Modified Release, 14 Capsules

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>..</td>
<td>..</td>
<td>54.81</td>
<td>37.70</td>
<td>MS Mono [MF]</td>
</tr>
</tbody>
</table>

#### Morphine Sulfate 15 mg Tablet: Modified Release, 28 Tablets

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>1</td>
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<td>..</td>
<td>24.57</td>
<td>25.72</td>
<td>MS Contin [MF]</td>
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#### Morphine Sulfate 20 mg Granules: Modified Release, 28 Sachets

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>1</td>
<td>..</td>
<td>..</td>
<td>60.63</td>
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<td>MS Contin Suspension 20 mg</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>[MF]</td>
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#### Morphine Sulfate 30 mg Capsule: Modified Release, 14 Capsules

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>1</td>
<td>..</td>
<td>..</td>
<td>24.56</td>
<td>25.71</td>
<td>MS Mono [MF]</td>
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#### Morphine Sulfate 30 mg Tablet: Modified Release, 28 Tablets

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
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<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>1</td>
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<td>36.23</td>
<td>37.38</td>
<td>* Momex SR 30 [QA]</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>* MORPHINE MR APOTEX [TX]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* MS Contin [MF]</td>
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#### Morphine Sulfate 5 mg Tablet: Modified Release, 28 Tablets

<table>
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<tr>
<th>Max Qty Packs</th>
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<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>1</td>
<td>..</td>
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<td>17.95</td>
<td>19.10</td>
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#### Morphine Sulfate 60 mg Capsule: Modified Release, 14 Capsules

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
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<tbody>
<tr>
<td>1</td>
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<td>..</td>
<td>36.21</td>
<td>37.36</td>
<td>MS Mono [MF]</td>
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#### Morphine Sulfate 60 mg Tablet: Modified Release, 28 Tablets

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
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<tbody>
<tr>
<td>1</td>
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<td>54.82</td>
<td>37.70</td>
<td>* Momex SR 60 [QA]</td>
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<tr>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>* MORPHINE MR APOTEX [TX]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* MS Contin [MF]</td>
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#### Morphine Sulfate 90 mg Capsule: Modified Release, 14 Capsules

<table>
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<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
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<th>DPMQ $</th>
<th>MRVSN $</th>
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<tbody>
<tr>
<td>1</td>
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<td>..</td>
<td>41.76</td>
<td>37.70</td>
<td>MS Mono [MF]</td>
</tr>
</tbody>
</table>
morphine hydrochloride 10 mg/mL oral liquid, 200 mL

5239R

Max Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer
---|---|---|---|---|---
1 | .. | 27.20 | 28.35 | Ordine 10 [MF]

morphine hydrochloride 2 mg/mL oral liquid, 200 mL

5237P

Max Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer
---|---|---|---|---|---
1 | .. | 20.67 | 21.82 | Ordine 2 [MF]

morphine hydrochloride 5 mg/mL oral liquid, 200 mL

5238Q

Max Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer
---|---|---|---|---|---
1 | .. | 23.07 | 24.22 | Ordine 5 [MF]

morphine sulfate 30 mg tablet, 20

5163R

Max Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer
---|---|---|---|---|---
1 | .. | 14.37 | 15.52 | Anamorph [FM]

**OXYCODONE**

**Caution**
The risk of drug dependence is high.

**Restricted benefit**
Severe disabling pain

**Clinical criteria:**
The condition must be unresponsive to non-narcotic analgesics.

**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.

**Oxycodone 30 mg suppository, 12**

2481N

Max Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer
---|---|---|---|---|---
1 | .. | 44.00 | 37.70 | Proladone [PL]

**Oxycodone hydrochloride 10 mg capsule, 20**

8501K

Max Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer
---|---|---|---|---|---
1 | .. | 14.76 | 15.91 | OxyNorm [MF]

**Oxycodone hydrochloride 20 mg capsule, 20**

8502L

Max Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer
---|---|---|---|---|---
1 | .. | 18.72 | 19.87 | OxyNorm [MF]

**Oxycodone hydrochloride 5 mg capsule, 20**

8464L

Max Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer
---|---|---|---|---|---
1 | .. | 12.14 | 13.29 | OxyNorm [MF]

**Oxycodone hydrochloride 5 mg tablet, 20**

2622B

Max Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer
---|---|---|---|---|---
1 | .. | 12.14 | 13.29 | Endone [QA]

**Oxycodone hydrochloride 5 mg/5 mL oral liquid, 250 mL**

8644Y

Max Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer
---|---|---|---|---|---
1 | .. | 21.07 | 22.22 | OxyNorm Liquid 5mg/5mL [MF]

**OXYCODONE**

**Caution**
The risk of drug dependence is high.


**NERVOUS SYSTEM**

**Schedule of Pharmaceutical Benefits**

**General**

**Restricted benefit**

Severe disabling pain

**Clinical criteria:**

The condition must be unresponsive to non-narcotic analgesics.

**Note**

Prescribing of drugs of addiction by dentists is not permitted in some States/Territories.

---

**OXYCODONE**

**Caution**

The risk of drug dependence is high.

**Restricted benefit**

Chronic severe disabling pain

**Clinical criteria:**

The condition must be unresponsive to non-narcotic analgesics.

**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.

OxyContin modified release tablets are intended to be crush-deterrent and to reduce the rapid release of oxycodone upon accidental or intentional misuse.

<table>
<thead>
<tr>
<th>oxycodone 30 mg suppository, 12</th>
</tr>
</thead>
<tbody>
<tr>
<td>Max Qty Packs</td>
</tr>
<tr>
<td>----------------</td>
</tr>
<tr>
<td>5194J</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>oxycodone hydrochloride 10 mg capsule, 20</th>
</tr>
</thead>
<tbody>
<tr>
<td>Max Qty Packs</td>
</tr>
<tr>
<td>----------------</td>
</tr>
<tr>
<td>5197M</td>
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<table>
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<thead>
<tr>
<th>oxycodone hydrochloride 5 mg/5 mL oral liquid, 250 mL</th>
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<tr>
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<tr>
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<tr>
<td>5190E</td>
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---

**OXYCODONE**

**Caution**

The risk of drug dependence is high.

**Restricted benefit**

Chronic severe disabling pain

**Clinical criteria:**

The condition must be unresponsive to non-narcotic analgesics.

**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.

OxyContin modified release tablets are intended to be crush-deterrent and to reduce the rapid release of oxycodone upon accidental or intentional misuse.

<table>
<thead>
<tr>
<th>oxycodone hydrochloride 10 mg tablet: modified release, 28 tablets</th>
</tr>
</thead>
<tbody>
<tr>
<td>Max Qty Packs</td>
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<table>
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<tr>
<td>----------------</td>
</tr>
<tr>
<td>8386J</td>
</tr>
</tbody>
</table>
NERVOUS SYSTEM

- **OXYCODEONE +NALOXONE**

  **Caution**
  The risk of drug dependence is high.

  **Restricted benefit**
  Chronic severe disabling pain

  **Clinical criteria:**
  The condition must be unresponsive to non-narcotic analgesics.

  **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.

  **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**

  **CODEINE PHOSPHATE with PARACETAMOL Tablet 30 mg-500 mg, 20**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>1</td>
<td>..</td>
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<td></td>
<td>&quot;APO- Paracetamol/Codeine 500/30 [TX]&quot;</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>&quot;Codapane Forte [AL]&quot;</td>
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<tr>
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<td></td>
<td></td>
<td>&quot;Paracetamol/Codeine GH 500/30 [GQ]&quot;</td>
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<td>&quot;Coffmar Forte [SZ]&quot;</td>
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<td></td>
<td>&quot;Prodeine Forte [AV]&quot;</td>
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<td>10.08</td>
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<td>&quot;Panadeine Forte [SW]&quot;</td>
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</table>

  **Note**
NERVOUS SYSTEM

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.

CODEINE PHOSPHATE with PARACETAMOL Tablet 30 mg-500 mg, 20

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
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<td>7.68</td>
<td>8.83</td>
<td></td>
<td>* Brand Name and Manufacturer</td>
</tr>
</tbody>
</table>

- **PARACETAMOL + CODEINE**
  - **Authority required**
  - Severe disabling pain
  - **Clinical criteria:**
    - The condition must be unresponsive to non-narcotic analgesics.
  - **Note**
    - Each authority approval will be limited to no more than 240 tablets per month for no more than 6 months.

CODEINE PHOSPHATE with PARACETAMOL Tablet 30 mg-500 mg, 20

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
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<tbody>
<tr>
<td>8785J</td>
<td></td>
<td></td>
<td>*9.52</td>
<td>10.67</td>
<td>* Brand Name and Manufacturer</td>
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</table>

Phenylpiperidine derivatives

- **FENTANYL**
  - **Caution**
    - The risk of drug dependence is high.
  - **Restricted benefit**
    - Chronic severe disabling pain
  - **Clinical criteria:**
    - The condition must be unresponsive to non-narcotic analgesics.
  - **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.

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 form fentanyl 12 microgram/hour patch are equivalent for the purposes of substitution.

Pharmaceutical benefits that have the form fentanyl 25 microgram/hour patch are equivalent for the purposes of substitution.

Pharmaceutical benefits that have the form fentanyl 50 microgram/hour patch are equivalent for the purposes of substitution.

Pharmaceutical benefits that have the form fentanyl 75 microgram/hour patch are equivalent for the purposes of substitution.

Pharmaceutical benefits that have the form fentanyl 100 microgram/hour patch are equivalent for the purposes of substitution.

fentanyl 100 microgram/hour patch, 5

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>5280X</td>
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<td>69.30</td>
<td>37.70</td>
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<td>* Brand Name and Manufacturer</td>
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fentanyl 100 microgram/hour patch, 5

<table>
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<tr>
<th>Max.Qty Packs</th>
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<th>Premium $</th>
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Schedule of Pharmaceutical Benefits
### NERVOUS SYSTEM

**fentanyl 100 microgram/hour patch, 5**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
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<th>DPMO $</th>
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**fentanyl 12 microgram/hour patch, 5**

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**fentanyl 12 microgram/hour patch, 5**

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**fentanyl 25 microgram/hour patch, 5**

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**fentanyl 25 microgram/hour patch, 5**

<table>
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**fentanyl 25 microgram/hour patch, 5**

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**fentanyl 50 microgram/hour patch, 5**

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**fentanyl 50 microgram/hour patch, 5**

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<td>37.70</td>
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**fentanyl 50 microgram/hour patch, 5**

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**fentanyl 75 microgram/hour patch, 5**

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**fentanyl 75 microgram/hour patch, 5**

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<td>57.81</td>
<td>37.70</td>
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</table>

**Diphenylpropylamine derivatives**

### METHADONE

**Caution**

The risk of drug dependence is high.

**Restricted benefit**

Severe disabling pain

**Clinical criteria:**

The condition must be unresponsive to non-narcotic analgesics.

**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

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440 NERVOUS SYSTEM
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.

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.

methadone hydrochloride 10 mg tablet, 20
1609Q
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<thead>
<tr>
<th>Max.Qty Packs</th>
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<th>Premium $</th>
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<th>MRVSN $</th>
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<tbody>
<tr>
<td>1</td>
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<td>..</td>
<td>15.57</td>
<td>16.72</td>
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methadone hydrochloride 10 mg/mL injection, 5 x 1 mL ampoules
1606M
<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
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<th>DPMQ $</th>
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<td>49.65</td>
<td>37.70</td>
<td>Physeptone [QA]</td>
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</table>

Oripavine derivatives

- **BUPRENORPHINE**

**Caution**
The risk of drug dependence is high.

**Restricted benefit**
Chronic severe disabling pain

**Clinical criteria:**
The condition must be unresponsive to non-narcotic analgesics.

**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.

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.

buprenorphine 10 microgram/hour patch, 2
8866P
<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
<th>No. of Rpts</th>
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<th>DPMQ $</th>
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<tr>
<td>1</td>
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<td>..</td>
<td>41.11</td>
<td>37.70</td>
<td>Norspan [MF]</td>
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buprenorphine 20 microgram/hour patch, 2
8867Q
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<th>DPMQ $</th>
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buprenorphine 5 microgram/hour patch, 2
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<th>No. of Rpts</th>
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<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tr>
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<td>..</td>
<td>..</td>
<td>27.04</td>
<td>28.19</td>
<td>Norspan [MF]</td>
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</tbody>
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Other opioids

- **TAPENTADOL**

**Caution**
The risk of drug dependence is high.

**Restricted benefit**
Chronic severe disabling pain

**Clinical criteria:**
The condition must be unresponsive to non-narcotic analgesics.

**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.

tapentadol 100 mg tablet: modified release, 28

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>10094G</td>
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tapentadol 150 mg tablet: modified release, 28

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<td>Palexia SR [CS]</td>
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tapentadol 200 mg tablet: modified release, 28

<table>
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<th>Max.Qty Packs</th>
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<th>DPMQ $</th>
<th>MRVSN $</th>
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<tbody>
<tr>
<td>10091D</td>
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<td>47.49</td>
<td>37.70</td>
<td>Palexia SR [CS]</td>
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tapentadol 250 mg tablet: modified release, 28

<table>
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<td>Palexia SR [CS]</td>
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tapentadol 50 mg tablet: modified release, 28

<table>
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<td>22.60</td>
<td>23.75</td>
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**TRAMADOL**

**Restricted benefit**

For pain where aspirin and/or paracetamol alone are inappropriate or have failed

tramadol hydrochloride 100 mg/mL oral liquid, 10 mL

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
<th>No. of Rpts</th>
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<tr>
<td>5150C</td>
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<td>14.05</td>
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**TRAMADOL**

**Restricted benefit**

Short-term treatment of acute pain

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

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
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<tbody>
<tr>
<td>5231H</td>
<td></td>
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<td>11.92</td>
<td>13.07</td>
<td>* Tramadol ACT [GN]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Tramadol Sandoz [SZ]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Tramal 100 [CS]</td>
</tr>
</tbody>
</table>

**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.

tramadol hydrochloride 100 mg tablet: modified release, 20 tablets

<table>
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<tr>
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<td>* GA Tramadol SR 100mg [GN]</td>
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<td></td>
<td></td>
<td></td>
<td>* Terry White Chemists</td>
</tr>
<tr>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>Tramadol SR [TW]</td>
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<tr>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>* Tramadol Sandoz SR [SZ]</td>
</tr>
<tr>
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<td></td>
<td></td>
<td>* Chem mart Tramadol SR [CH]</td>
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<td></td>
<td>* Lodam SR 100 [ZP]</td>
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<td></td>
<td></td>
<td>* Tramadol AN SR [EA]</td>
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<td>* Tramadol SR generichealth [GQ]</td>
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</table>
### NERVOUS SYSTEM

**Schedule of Pharmaceutical Benefits**

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<table>
<thead>
<tr>
<th>Tramadol Hydrochloride 100 mg/mL Oral Liquid, 10 mL</th>
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</thead>
<tbody>
<tr>
<td><strong>Tramedo SR 100 [AF]</strong></td>
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<tr>
<td><strong>Zydol SR 100 [QA]</strong></td>
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<table>
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<tr>
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<td><strong>Zydol SR 150 [QA]</strong></td>
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<table>
<thead>
<tr>
<th>Tramadol Hydrochloride 200 mg Tablet: Modified Release, 20 Tablets</th>
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<tr>
<td><strong>Tramedo SR 200 [AF]</strong></td>
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<td><strong>Zydol SR 200 [QA]</strong></td>
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<tr>
<td><strong>Tramedo SR 50 [AF]</strong></td>
</tr>
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</table>

---

**TRAMADOL**

**Restricted benefit**

For acute pain where aspirin and/or paracetamol alone are inappropriate or have failed

**Restricted benefit**

For dosage titration in chronic pain where aspirin and/or paracetamol alone are inappropriate or have failed

---

### TRAMADOL

**Restricted benefit**

For acute pain where aspirin and/or paracetamol alone are inappropriate or have failed

**Note**

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

---

**TRAMADOL**

**Restricted benefit**

Short-term treatment of acute pain

**Note**
NERVOUS SYSTEM

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

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

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
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<th>Brand Name and Manufacturer</th>
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<tr>
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<td>13.07</td>
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<td>* Tramadol Sandoz [SZ]</td>
</tr>
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</table>

- TRAMADOL

**Restricted benefit**

For dosage titration in chronic pain where aspirin and/or paracetamol alone are inappropriate or have failed

**Note**

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

tramadol hydrochloride 50 mg capsule, 20

<table>
<thead>
<tr>
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<th>No. of Rpts</th>
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<td>* Chem mart Tramadol [CH]</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>* GA Tramadol 50mg [GN]</td>
<td>* Terry White Chemists</td>
</tr>
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<td></td>
<td>* Tramadol Actavis [UA]</td>
<td>* Tramadol AN [EA]</td>
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<td></td>
<td></td>
<td></td>
<td>* Tramadol Sandoz [SZ]</td>
<td>* Tramadol SCP [CR]</td>
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<td></td>
<td></td>
<td>* Tramedo [AF]</td>
<td>* Zydol [QA]</td>
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<td></td>
<td>* Tramal [CS]</td>
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OTHER ANALGESICS AND ANTIPYRETICS

- **Salicylic acid and derivatives**

- **ASPIRIN**

aspirin 300 mg tablet: effervescent, 96

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
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<tbody>
<tr>
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<td>8.51</td>
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<td>Solprin [RC]</td>
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aspirin 300 mg tablet: effervescent, 96

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
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<td>9.66</td>
<td>Solprin [RC]</td>
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</table>

- **Paracetamol**

paracetamol 120 mg/5 mL oral liquid, 100 mL

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
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<td>9.72</td>
<td>10.87</td>
<td>Panamax [SW]</td>
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paracetamol 120 mg/5 mL oral liquid, 100 mL

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
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<th>Premium $</th>
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<td>9.72</td>
<td>10.87</td>
<td>Panamax [SW]</td>
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paracetamol 240 mg/5 mL oral liquid, 200 mL

<table>
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paracetamol 240 mg/5 mL oral liquid, 200 mL

<table>
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<th>Max Qty Packs</th>
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paracetamol 500 mg tablet, 100

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<td>8.66</td>
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<td>* APO-Paracetamol [TX]</td>
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<tr>
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<td></td>
<td>* Generic Health Pty Ltd [GQ]</td>
</tr>
<tr>
<td></td>
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<td></td>
<td></td>
<td>* Paracetamol (Sandoz) [SZ]</td>
</tr>
<tr>
<td></td>
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<td></td>
<td></td>
<td></td>
<td>* Parapane [AF]</td>
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paracetamol 500 mg tablet, 100

<table>
<thead>
<tr>
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<td>8.66</td>
<td>9.81</td>
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<td></td>
<td></td>
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<td></td>
<td>* Generic Health Pty Ltd [GQ]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Paracetamol (Sandoz) [SZ]</td>
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</tbody>
</table>
**NERVOUS SYSTEM**

- **PARACETAMOL**
  - **Restricted benefit**
  - Persistent pain
  - Clinical criteria:
The condition must be associated with osteoarthritis.

  **paracetamol 665 mg tablet: modified release, 96 tablets**

<table>
<thead>
<tr>
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<td>2</td>
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<td>15.34</td>
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- **PARACETAMOL**
  - **Restricted benefit**
  - Chronic arthropathies

  **paracetamol 500 mg tablet, 100**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
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<tbody>
<tr>
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<td>12.46</td>
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<td></td>
<td>*Generic Health Pty Ltd [GQ]</td>
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<td>*Paracetamol (Sandoz) [SZ]</td>
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  **paracetamol 500 mg tablet, 100**

<table>
<thead>
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<td>*Paracetamol (Sandoz) [SZ]</td>
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<td></td>
<td>*Parapane [AF]</td>
</tr>
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</table>

- **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.

  **pregabalin 150 mg capsule, 56**

<table>
<thead>
<tr>
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<th>Premium $</th>
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<tbody>
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<td>1</td>
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  **pregabalin 25 mg capsule, 56**

<table>
<thead>
<tr>
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<th>DPMQ $</th>
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<td>Lyrica [PF]</td>
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  **pregabalin 300 mg capsule, 56**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
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<tbody>
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<td>37.70</td>
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<td>Lyrica [PF]</td>
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  **pregabalin 75 mg capsule, 56**

<table>
<thead>
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<tr>
<td>1</td>
<td>5</td>
<td>49.11</td>
<td>37.70</td>
<td></td>
<td>Lyrica [PF]</td>
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</table>

- **ANTIMIGRAINE PREPARATIONS**
  - **Selective serotonin (5HT1) agonists**

- **ELETRIPTAN**
  - **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.

**Authority required (STREAMLINED)**

**4573**

Migraine attack

**Clinical criteria:**

The condition must have usually failed to respond to analgesics in the past.

**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.

**Continuing Therapy Only:**

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

<table>
<thead>
<tr>
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<table>
<thead>
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<tbody>
<tr>
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</tr>
<tr>
<td>Max Qty Packs</td>
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<tr>
<td>1 5</td>
</tr>
</tbody>
</table>

**NARATRIPTAN**

**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.

**Authority required**

Migraine attack

**Clinical criteria:**

The condition must have usually failed to respond to analgesics in the past.

**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.

**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>naratriptan 2.5 mg tablet, 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>8298R</td>
</tr>
<tr>
<td>Max Qty Packs</td>
</tr>
<tr>
<td>2 5</td>
</tr>
</tbody>
</table>

**NARATRIPTAN**

**Caution**

Naratriptan is contraindicated in patients with known or suspected coronary artery disease. The drug should not be used within 24 hours of ergotamine or dihydroergotamine use.

**Authority required**

Migraine attack in a patient where attacks in the past have usually failed to respond to analgesics, and where adverse events have occurred with other suitable PBS-listed drugs

**Authority required**

Migraine attack in a patient where attacks in the past have usually failed to respond to analgesics, and where drug interactions have occurred with other suitable PBS-listed drugs

**Authority required**

Migraine attack in a patient where attacks in the past have usually failed to respond to analgesics, and where drug interactions are expected to occur with other suitable PBS-listed drugs

**Authority required**

Migraine attack in a patient where attacks in the past have usually failed to respond to analgesics, and where transfer to another suitable PBS-listed drug would cause patient confusion resulting in problems with compliance

**Authority required**

Migraine attack in a patient where attacks in the past have usually failed to respond to analgesics, and where transfer to another suitable PBS-listed drug is likely to result in adverse clinical consequences

**Note**

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

**Continuing Therapy Only:**
Nervous System

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

**Naratriptan 2.5 mg tablet, 2**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>9734H</td>
<td>2</td>
<td>5</td>
<td>*29.02</td>
<td>30.17</td>
<td>Naramig [AS]</td>
</tr>
</tbody>
</table>

**Rizatriptan**

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.

Authority required (STREAMLINED)

4573

Migraine attack

Clinical criteria:
The condition must have usually failed to respond to analgesics in the past.

Note

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

Continuing Therapy Only:

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

**Rizatriptan 10 mg wafer, 2**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>9313E</td>
<td>2</td>
<td>5</td>
<td>*25.46</td>
<td>26.61</td>
<td>Maxalt [MK]</td>
</tr>
</tbody>
</table>

**Sumatriptan**

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.

Authority required (STREAMLINED)

4558

Migraine attack

Clinical criteria:
The condition must have usually failed to respond to analgesics in the past.

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.

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.

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.

**Sumatriptan Tablet (fast disintegrating) 50 mg (as succinate), 2**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>8885P</td>
<td>2</td>
<td>5</td>
<td>*2.04</td>
<td>16.76</td>
<td>* Imigran FDT [AS]</td>
</tr>
</tbody>
</table>

**Sumatriptan Tablet 50 mg (as succinate), 2**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>8144P</td>
<td>2</td>
<td>5</td>
<td>*14.72</td>
<td>15.87</td>
<td>* APO-Sumatriptan [TX]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Iptam [AL]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Sumatriptan Sandoz [SZ]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Chem mart Sumatriptan [CH]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Sumagran Aspen 50 [AS]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Sumatran [QA]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Terry White Chemists</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Sumatriptan [TW]</td>
</tr>
</tbody>
</table>

**Sumatriptan 20 mg/actuation nasal spray, 2 actuations**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>8341B</td>
<td>1</td>
<td>5</td>
<td>19.59</td>
<td>20.74</td>
<td>Imigran [AS]</td>
</tr>
</tbody>
</table>
### Zolmitriptan

**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.

**Authority required (STREAMLINED)**

- **Migraine attack**
- **Clinical criteria:**
  The condition must have usually failed to respond to analgesics in the past.

**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.

**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.

### Cyproheptadine

**Restricted benefit**
Prevention of migraine

**Note**
Cyproheptadine hydrochloride is not PBS-subsidised for use in hay fever or atopy.

**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.

### 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.

### Antiepileptics

- **Antiepileptics**
- **Barbiturates and derivatives**
### PHENOBARBITONE

**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.

<table>
<thead>
<tr>
<th>Product Description</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phenobarbitone 30 mg tablet, 200</td>
<td>1850J</td>
<td>1</td>
<td>..</td>
<td>16.94</td>
<td>18.09</td>
<td>Aspen Pharma Pty Ltd [QA]</td>
</tr>
<tr>
<td>Phenobarbitone sodium 219 mg/mL injection, 5 x 1 mL ampoules</td>
<td>2138M</td>
<td>1</td>
<td>..</td>
<td>39.36</td>
<td>37.70</td>
<td>Fawns and McAllan Proprietary Limited [FM]</td>
</tr>
</tbody>
</table>

### 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.

<table>
<thead>
<tr>
<th>Product Description</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primidone 250 mg tablet, 200</td>
<td>1939C</td>
<td>1</td>
<td>2</td>
<td>83.83</td>
<td>37.70</td>
<td>Mysoline [LM]</td>
</tr>
</tbody>
</table>

### PHENYTOIN derivatives

**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>Product Description</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phenytoin 30 mg/5 mL oral liquid, 500 mL</td>
<td>2692Q</td>
<td>1</td>
<td>3</td>
<td>30.62</td>
<td>31.77</td>
<td>Dilantin [PF]</td>
</tr>
<tr>
<td>Phenytoin 50 mg tablet: chewable, 200</td>
<td>1249R</td>
<td>1</td>
<td>2</td>
<td>48.49</td>
<td>37.70</td>
<td>Dilantin Infatabs [PF]</td>
</tr>
<tr>
<td>Phenytoin sodium 100 mg capsule, 200</td>
<td>1874P</td>
<td>1</td>
<td>2</td>
<td>30.46</td>
<td>31.61</td>
<td>Dilantin Sodium [PF]</td>
</tr>
<tr>
<td>Phenytoin sodium 30 mg capsule, 200</td>
<td>1873N</td>
<td>1</td>
<td>2</td>
<td>29.52</td>
<td>30.67</td>
<td>Dilantin Sodium [PF]</td>
</tr>
</tbody>
</table>

### Succinimide derivatives

**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>Product Description</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ethosuximide 250 mg capsule, 200</td>
<td>1413J</td>
<td>1</td>
<td>2</td>
<td>66.18</td>
<td>37.70</td>
<td>Zarontin [PF]</td>
</tr>
</tbody>
</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.

<table>
<thead>
<tr>
<th>clonazepam 1 mg/mL injection [5 x 1 mL ampoules] (&amp;) inert substance diluent [5 x 1 mL ampoules], 1 pack</th>
</tr>
</thead>
<tbody>
<tr>
<td>1807D</td>
</tr>
<tr>
<td>1</td>
</tr>
</tbody>
</table>

#### Caution

Abuse of clonazepam has been reported. Refer to the current product information.

**Authority required**

Neurologically proven 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.

<table>
<thead>
<tr>
<th>clonazepam 2 mg tablet, 100</th>
</tr>
</thead>
<tbody>
<tr>
<td>1806C</td>
</tr>
<tr>
<td>2</td>
</tr>
<tr>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>clonazepam 2.5 mg/mL oral liquid, 10 mL</th>
</tr>
</thead>
<tbody>
<tr>
<td>1808E</td>
</tr>
<tr>
<td>2</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>clonazepam 500 microgram tablet, 100</th>
</tr>
</thead>
<tbody>
<tr>
<td>1805B</td>
</tr>
<tr>
<td>2</td>
</tr>
<tr>
<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 and who have been demonstrated, within the past 6 months, to be benzodiazepine dependent by an unsuccessful attempt at gradual withdrawal

**Authority required**

For use by a patient who is receiving long-term nursing care and in respect of whom a Carer Allowance is payable as a disabled adult and who has been demonstrated, within the past 6 months, to be benzodiazepine dependent by an unsuccessful attempt at gradual withdrawal

**Note**

Continuing Therapy Only:

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>nitrazepam 5 mg tablet, 25</th>
</tr>
</thead>
<tbody>
<tr>
<td>2732T</td>
</tr>
<tr>
<td>2</td>
</tr>
</tbody>
</table>
# NERVOUS SYSTEM

## Schedule of Pharmaceutical Benefits

### Carboxamide derivatives

### CARBAMAZEPINE

<table>
<thead>
<tr>
<th>CARBAMAZEPINE Tablet 100 mg, 100</th>
</tr>
</thead>
<tbody>
<tr>
<td>5039F</td>
</tr>
<tr>
<td>Max.Qty Packs</td>
</tr>
<tr>
<td>2</td>
</tr>
</tbody>
</table>

**Carbamazepine 100 mg/5 mL oral liquid, 300 mL**

<table>
<thead>
<tr>
<th>max39f</th>
</tr>
</thead>
<tbody>
<tr>
<td>5041H</td>
</tr>
<tr>
<td>max qty</td>
</tr>
<tr>
<td>1</td>
</tr>
</tbody>
</table>

**Carbamazepine 200 mg tablet: modified release, 200 tablets**

<table>
<thead>
<tr>
<th>max39f</th>
</tr>
</thead>
<tbody>
<tr>
<td>5038E</td>
</tr>
<tr>
<td>max qty</td>
</tr>
<tr>
<td>1</td>
</tr>
</tbody>
</table>

**Carbamazepine 400 mg tablet: modified release, 200 tablets**

<table>
<thead>
<tr>
<th>max39f</th>
</tr>
</thead>
<tbody>
<tr>
<td>5037D</td>
</tr>
<tr>
<td>max qty</td>
</tr>
<tr>
<td>1</td>
</tr>
</tbody>
</table>

### CARBAMAZEPINE

**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.

**Carbamazepine 100 mg/5 mL oral liquid, 300 mL**

<table>
<thead>
<tr>
<th>max39f</th>
</tr>
</thead>
<tbody>
<tr>
<td>2427R</td>
</tr>
<tr>
<td>max qty</td>
</tr>
<tr>
<td>1</td>
</tr>
</tbody>
</table>

**Carbamazepine 200 mg tablet: modified release, 200 tablets**

<table>
<thead>
<tr>
<th>max39f</th>
</tr>
</thead>
<tbody>
<tr>
<td>2426Q</td>
</tr>
<tr>
<td>max qty</td>
</tr>
<tr>
<td>1</td>
</tr>
</tbody>
</table>

**Carbamazepine 400 mg tablet: modified release, 200 tablets**

<table>
<thead>
<tr>
<th>max39f</th>
</tr>
</thead>
<tbody>
<tr>
<td>2431Y</td>
</tr>
<tr>
<td>max qty</td>
</tr>
<tr>
<td>1</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.

**Carbamazepine Tablet 200 mg, 100**

<table>
<thead>
<tr>
<th>max39f</th>
</tr>
</thead>
<tbody>
<tr>
<td>1724R</td>
</tr>
<tr>
<td>max qty</td>
</tr>
<tr>
<td>2</td>
</tr>
</tbody>
</table>

**Carbamazepine 200 mg tablet, 200**

<table>
<thead>
<tr>
<th>max39f</th>
</tr>
</thead>
<tbody>
<tr>
<td>5040G</td>
</tr>
<tr>
<td>max qty</td>
</tr>
<tr>
<td>1</td>
</tr>
</tbody>
</table>

### CARBAMAZEPINE

**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.

**Carbamazepine Tablet 100 mg, 100**

<table>
<thead>
<tr>
<th>max39f</th>
</tr>
</thead>
<tbody>
<tr>
<td>2422L</td>
</tr>
<tr>
<td>max qty</td>
</tr>
<tr>
<td>2</td>
</tr>
</tbody>
</table>
NERVOUS SYSTEM

CARBAMAZEPINE

Note
For item codes 2419H and 1706T, pharmaceutical benefits that have the form tablet 200 mg are equivalent for the purposes of substitution.

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.

CARBAMAZEPINE Tablet 200 mg, 100

<table>
<thead>
<tr>
<th>Code</th>
<th>Max.Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1706T</td>
<td>2</td>
<td>2</td>
<td>..</td>
<td>*29.34</td>
<td>30.49</td>
<td>* Carbamazepine Sandoz [SZ]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>2.96</td>
<td>*32.30</td>
<td>30.49</td>
<td>* Tegretol 200 [NV]</td>
</tr>
</tbody>
</table>

Carbamazepine 200 mg tablet, 200

<table>
<thead>
<tr>
<th>Code</th>
<th>Max.Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>2419H</td>
<td>1</td>
<td>2</td>
<td>..</td>
<td>29.33</td>
<td>30.48</td>
<td>* Teril [AF]</td>
</tr>
</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
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.

Oxcarbazepine 150 mg tablet, 100

<table>
<thead>
<tr>
<th>Code</th>
<th>Max.Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>8584T</td>
<td>1</td>
<td>5</td>
<td>..</td>
<td>72.61</td>
<td>37.70</td>
<td>Triepal [NV]</td>
</tr>
</tbody>
</table>

Oxcarbazepine 300 mg tablet, 100

<table>
<thead>
<tr>
<th>Code</th>
<th>Max.Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>8585W</td>
<td>1</td>
<td>5</td>
<td>..</td>
<td>115.42</td>
<td>37.70</td>
<td>Triepal [NV]</td>
</tr>
</tbody>
</table>

Oxcarbazepine 60 mg/mL oral liquid, 250 mL

<table>
<thead>
<tr>
<th>Code</th>
<th>Max.Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>8588B</td>
<td>2</td>
<td>5</td>
<td>..</td>
<td>*138.46</td>
<td>37.70</td>
<td>Triepal [NV]</td>
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Oxcarbazepine 600 mg tablet, 100

<table>
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<th>Premium $</th>
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<th>MRVSN $</th>
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</thead>
<tbody>
<tr>
<td>8586X</td>
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<td>5</td>
<td>..</td>
<td>188.32</td>
<td>37.70</td>
<td>Triepal [NV]</td>
</tr>
</tbody>
</table>

Fatty acid derivatives

TIAGABINE

Authority required (STREAMLINED)

4928

Partial epileptic seizures

Clinical criteria:
The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs.

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.

tiagabine 10 mg tablet, 50

<table>
<thead>
<tr>
<th>Code</th>
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<th>No. of Rpts</th>
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<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
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<td>5</td>
<td>..</td>
<td>*139.18</td>
<td>37.70</td>
<td>Gabitril [OA]</td>
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</table>

tiagabine 15 mg tablet, 50

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<tr>
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<td>5</td>
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<td>*197.24</td>
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<td>Gabitril [OA]</td>
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</table>
NERVOUS SYSTEM

Schedule of Pharmaceutical Benefits

<table>
<thead>
<tr>
<th>tiagabine 5 mg tablet, 50</th>
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<tbody>
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</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>valproate sodium 100 mg tablet, 100</th>
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</thead>
<tbody>
<tr>
<td>Max Qty Packs</td>
</tr>
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<table>
<thead>
<tr>
<th>valproate sodium 200 mg tablet: enteric, 100</th>
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<tbody>
<tr>
<td>Max Qty Packs</td>
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<table>
<thead>
<tr>
<th>valproate sodium 200 mg/5 mL oral liquid, 300 mL</th>
</tr>
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<tbody>
<tr>
<td>Max Qty Packs</td>
</tr>
<tr>
<td>2</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>valproate sodium 200 mg/5 mL oral liquid, 300 mL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Max Qty Packs</td>
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<td>2</td>
</tr>
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</table>

<table>
<thead>
<tr>
<th>valproate sodium 500 mg tablet: enteric, 100</th>
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<tbody>
<tr>
<td>Max Qty Packs</td>
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<tr>
<td>2</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
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</tr>
</tbody>
</table>

**VIGABATRIN**

- **Caution**
  Visual field defects have been reported with this drug.

**Authority required (STREAMLINED)**

4929 Epileptic seizures

**Clinical criteria:**
The condition must have failed to be 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.

<table>
<thead>
<tr>
<th>vigabatrin 500 mg oral liquid: powder for, 60 x 500 mg sachets</th>
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<tbody>
<tr>
<td>Max Qty Packs</td>
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<tr>
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<table>
<thead>
<tr>
<th>vigabatrin 500 mg tablet, 100</th>
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<tr>
<td>Max Qty Packs</td>
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<tr>
<td>1</td>
</tr>
</tbody>
</table>

**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.

gabapentin 100 mg capsule, 100

Max Qty Packs | No. of Rpts | Premium | DPMQ | MRVSN | Brand Name and Manufacturer | Brand Name and Manufacturer
--- | --- | --- | --- | --- | --- | ---
8505P | 1 | 5 | .. | 12.95 | 14.10 | * APO-Gabapentin [TX] | * Gabapentin [NJ]
* Gabapentin Aspen 100 [FM] | * Neurontin 100 [AF]

 gabapentin 300 mg capsule, 100

Max Qty Packs | No. of Rpts | Premium | DPMQ | MRVSN | Brand Name and Manufacturer | Brand Name and Manufacturer
--- | --- | --- | --- | --- | --- | ---
1834M | 1 | 5 | .. | 27.43 | 28.58 | * Gabacor [NJ] | * Gabapentin [NJ]
* Gabapentin Aspen 300 [FM] | * Neurontin [PF]
* Gabapentin GH [GQ] | * Neurontin [PF]
* Gantin [GN] | * Neurontin [PF]

 gabapentin 400 mg capsule, 100

Max Qty Packs | No. of Rpts | Premium | DPMQ | MRVSN | Brand Name and Manufacturer | Brand Name and Manufacturer
--- | --- | --- | --- | --- | --- | ---
1835N | 1 | 5 | .. | 34.94 | 36.09 | * Gabacor [NJ] | * Gabapentin 400 [CR]
* Gabapentin Aspen 400 [FM] | * Gabapentin GH [GQ]
* Gabapentin Sandoz [SZ] | * Gantin [GN]
* GenRx Gabapentin [GX] | * Neurontin [PF]
* Nupentin 400 [AF] | * Neurontin [PF]

 gabapentin 600 mg tablet, 100

Max Qty Packs | No. of Rpts | Premium | DPMQ | MRVSN | Brand Name and Manufacturer | Brand Name and Manufacturer
--- | --- | --- | --- | --- | --- | ---
8559L | 1 | 5 | .. | 50.16 | 37.70 | * Gabapentin AN [EA] | * Gabapentin [NJ]
* Gabaran [RA] | * Neurontin [PF]
* Pharmacor Gabapentin 600 [CR] | * Neurontin [PF]

 gabapentin 800 mg tablet, 100

Max Qty Packs | No. of Rpts | Premium | DPMQ | MRVSN | Brand Name and Manufacturer | Brand Name and Manufacturer
--- | --- | --- | --- | --- | --- | ---
8389M | 1 | 5 | .. | 63.81 | 37.70 | * Gabapentin AN [EA] | * Gabapentin [NJ]
* Gabaran [RA] | * Neurontin [PF]
* GenRx Gabapentin [GX] | * Neurontin [PF]
* Nupentin Tabs [AF] | * Neurontin [PF]
* Pharmacor Gabapentin 800 [CR] | * Neurontin [PF]

**LACOSAMIDE**

Authority required (STREAMLINED)

4271
Intractable partial epileptic seizures

Treatment Phase: Initial

Clinical criteria:
The treatment must be in combination with two or more anti-epileptic drugs which includes one second-line adjunctive agent, **AND**
The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs, which includes at least one first-line anti-epileptic agent and at least two second-line adjunctive anti-epileptic agents, **AND**
The treatment must be for dose titration purposes.

Population criteria:
Patient must be aged 16 years or older.

Treatment criteria:
Must be treated by a neurologist.

Note
Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.
lacosamide 100 mg tablet, 14

<table>
<thead>
<tr>
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<th>DPMO $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>9334G</td>
<td>1</td>
<td>..</td>
<td>52.63</td>
<td>37.70</td>
<td>Vimpat [UC]</td>
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</table>

lacosamide 150 mg tablet, 14

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<thead>
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<th>DPMO $</th>
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<tr>
<td>9336J</td>
<td>1</td>
<td>..</td>
<td>75.03</td>
<td>37.70</td>
<td>Vimpat [UC]</td>
</tr>
</tbody>
</table>

lacosamide 50 mg tablet, 14

<table>
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<th>Premium $</th>
<th>DPMO $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>9333F</td>
<td>1</td>
<td>..</td>
<td>30.55</td>
<td>31.70</td>
<td>Vimpat [UC]</td>
</tr>
</tbody>
</table>

- **LACOSAMIDE**

  **Authority required (STREAMLINED)**

  4264
  
  Intractable partial epileptic seizures
  
  Treatment Phase: Initial
  
  **Clinical criteria:**
  
  The treatment must be in combination with two or more anti-epileptic drugs which includes one second-line adjunctive agent, 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.
  
  **Authority required (STREAMLINED)**

  4249
  
  Intractable partial epileptic seizures
  
  Treatment Phase: Continuing
  
  **Clinical criteria:**
  
  Patient must have previously been treated with PBS-subsidised lacosamide.
  
  **Population criteria:**
  
  Patient must be aged 16 years or older.

  **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.

lacosamide 100 mg tablet, 56

<table>
<thead>
<tr>
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<th>MRVSN $</th>
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<tbody>
<tr>
<td>9335H</td>
<td>1</td>
<td>5</td>
<td>188.80</td>
<td>37.70</td>
<td>Vimpat [UC]</td>
</tr>
</tbody>
</table>

- **LACOSAMIDE**

  **Authority required (STREAMLINED)**

  4240
  
  Intractable partial epileptic seizures
  
  Treatment Phase: Initial
  
  **Clinical criteria:**
  
  The treatment must be in combination with two or more anti-epileptic drugs which includes one second-line adjunctive agent, AND
  
  The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs, which includes at least one first-line anti-epileptic agent and at least two second-line adjunctive anti-epileptic agents.
  
  **Population criteria:**
  
  Patient must be aged 16 years or older.
  
  **Treatment criteria:**
  
  Must be treated by a neurologist.
  
  **Authority required (STREAMLINED)**

  4257
  
  Intractable partial epileptic seizures
  
  Treatment Phase: Continuing
  
  **Clinical criteria:**
  
  Patient must have previously been treated with PBS-subsidised lacosamide.
  
  **Population criteria:**
NERVOUS SYSTEM

Patient must be aged 16 years or older.

Note
No applications for increased maximum quantities will be authorised for the 56 tablet packs of the 150 mg and 200 mg strengths.

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>Therapy</th>
<th>Strength</th>
<th>Pack Size</th>
<th>Max.Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 lacosamide 150 mg tablet, 56</td>
<td>9337K</td>
<td>1 5</td>
<td>..</td>
<td>273.00</td>
<td>37.70</td>
<td>Vipat [UC]</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2 lacosamide 200 mg tablet, 56</td>
<td>9338L</td>
<td>1 5</td>
<td>..</td>
<td>355.72</td>
<td>37.70</td>
<td>Vipat [UC]</td>
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<td></td>
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</tbody>
</table>

LAMOTRIGINE

**Authority required (STREAMLINED)**

1426
Treatment of 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.

<table>
<thead>
<tr>
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<th>No. of Rpts</th>
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<th>DPMQ $</th>
<th>MRVSN $</th>
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<tbody>
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<td>8063J</td>
<td>1 5</td>
<td>..</td>
<td>11.21</td>
<td>12.36</td>
<td>* Lamotrigine [AF] * Seaze 5 [QA] * Lamotrigine Aspen 5 [FM]</td>
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</tr>
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</table>

NP

## 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.

### levetiracetam 1 g tablet, 60

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
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<th>DPMO</th>
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<tbody>
<tr>
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<td>..</td>
<td>76.03</td>
<td>37.70</td>
</tr>
</tbody>
</table>

* APO-Levetiracetam [TX]
* Kepct [GN]
* Keran 1000 [DO]
* Levactam [ER]
* Levetiracetam AN [EA]
* Levetiracetam SZ [SZ]
* Levitaccord [RA]
* Terry White Chemists Levetiracetam [TW]
* Chem mart Levetiracetam [CH]
* Keppra [UC]
* Kevtam [AF]
* Levetiracetam 1000 [RZ]
* Levetiracetam genericheath [GQ]
* Levi 1000 [FM]
* Levitam 1000 [QA]

### levetiracetam 250 mg tablet, 60

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<tr>
<th>Max Qty Packs</th>
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<th>MRVSN</th>
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* APO-Levetiracetam [TX]
* Kepct [GN]
* Keran 250 [DO]
* Levactam [ER]
* Levetiracetam AN [EA]
* Levetiracetam SZ [SZ]
* Levitaccord [RA]
* Terry White Chemists Levetiracetam [TW]
* Chem mart Levetiracetam [CH]
* Keppra [UC]
* Kevtam [AF]
* Levetiracetam 250 [RZ]
* Levetiracetam genericheath [GQ]
* Levi 250 [FM]
* Levitam 250 [QA]

### levetiracetam 500 mg tablet, 60

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* APO-Levetiracetam [TX]
* Kepct [GN]
* Keran 500 [DO]
* Levactam [ER]
* Levetiracetam AN [EA]
* Levetiracetam SZ [SZ]
* Levitaccord [RA]
* Terry White Chemists Levetiracetam [TW]
* Chem mart Levetiracetam [CH]
* Keppra [UC]
* Kevtam [AF]
* Levetiracetam 500 [RZ]
* Levetiracetam genericheath [GQ]
* Levi 500 [FM]
* Levitam 500 [QA]

## LEVETIRACETAM

**Authority required (STREAMLINED)**

### 3291

Treatment of partial epileptic seizures, which are not controlled satisfactorily by other anti-epileptic drugs in a patient unable to take a solid dose form of levetiracetam

**Note**

Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and 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.

**levetiracetam 100 mg/mL oral liquid, 300 mL**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>5</td>
<td>..</td>
<td>111.76</td>
<td>37.70</td>
<td>Keppra [UC]</td>
</tr>
</tbody>
</table>

**PERAMPANEL**

Authority required (STREAMLINED)

4656

Intractable partial epileptic seizures

Treatment Phase: Initial

Clinical criteria:
The treatment must be in combination with two or more anti-epileptic drugs which includes one second-line adjunctive agent, AND

The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs, which includes at least one first-line anti-epileptic agent and at least two second-line adjunctive anti-epileptic agents.

Treatment criteria:
Must be treated by a neurologist.

**perampanel 2 mg tablet, 7**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
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</thead>
<tbody>
<tr>
<td>10157N</td>
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<td>52.64</td>
<td>37.70</td>
<td>Fycompa [EI]</td>
</tr>
</tbody>
</table>

**PERAMPANEL**

Authority required (STREAMLINED)

4658

Intractable partial epileptic seizures

Treatment Phase: Continuing

Clinical criteria:
Patient must have previously been issued with an authority prescription for this drug.

Note
Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and 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.

**perampanel 10 mg tablet, 28**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
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<th>DPMQ $</th>
<th>MRVSN $</th>
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</thead>
<tbody>
<tr>
<td>10151G</td>
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<td>5</td>
<td>355.72</td>
<td>37.70</td>
<td>Fycompa [EI]</td>
</tr>
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</table>

**perampanel 12 mg tablet, 28**

<table>
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<tr>
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<th>DPMQ $</th>
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<td>5</td>
<td>355.72</td>
<td>37.70</td>
<td>Fycompa [EI]</td>
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</table>

**perampanel 4 mg tablets, 28**

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<th>Premium $</th>
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<th>MRVSN $</th>
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<tbody>
<tr>
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**perampanel 6 mg tablet, 28**

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<thead>
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<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
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</thead>
<tbody>
<tr>
<td>10163X</td>
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<td>5</td>
<td>273.00</td>
<td>37.70</td>
<td>Fycompa [EI]</td>
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</tbody>
</table>

**perampanel 8 mg tablet, 28**

<table>
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<th>No. of Rpts</th>
<th>Premium $</th>
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<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>10160R</td>
<td>1</td>
<td>5</td>
<td>355.72</td>
<td>37.70</td>
<td>Fycompa [EI]</td>
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</tbody>
</table>

**SULTHIAME**

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.
sulthiame 200 mg tablet, 200

<table>
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<tbody>
<tr>
<td>2100M</td>
<td>1</td>
<td>2</td>
<td>206.33</td>
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<td>Ospolot [PL]</td>
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sulthiame 50 mg tablet, 200

<table>
<thead>
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<th>DPMQ $</th>
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<th>Brand Name and Manufacturer</th>
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<tr>
<td>2099L</td>
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<td>2</td>
<td>82.81</td>
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<td>Ospolot [PL]</td>
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</tbody>
</table>

**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

**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.

**topiramate 100 mg tablet, 60**

<table>
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<tr>
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<tbody>
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<td>47.17</td>
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<tr>
<td></td>
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<td></td>
<td></td>
<td></td>
<td>RBX Topiramate [RA]</td>
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<tr>
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<td></td>
<td></td>
<td></td>
<td>Topamax [JC]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Topiramate GH [GQ]</td>
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<tr>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>Epiramax 100 [QA]</td>
</tr>
<tr>
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<td></td>
<td></td>
<td></td>
<td>Tamate [AF]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
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<td>Topiramate AN [EA]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Topiramate Sandoz [SZ]</td>
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</tbody>
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**topiramate 200 mg tablet, 60**

<table>
<thead>
<tr>
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<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
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<td>5</td>
<td>73.13</td>
<td>37.70</td>
<td>APO-Topiramate [TX]</td>
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<tr>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>RBX Topiramate [RA]</td>
</tr>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Topamax [JC]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Topiramate GH [GQ]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Epiramax 200 [QA]</td>
</tr>
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<td></td>
<td></td>
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<td></td>
<td>Tamate [AF]</td>
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<tr>
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<td>Topiramate Sandoz [SZ]</td>
</tr>
</tbody>
</table>

**TOPIRAMATE**

*Authority required (STREAMLINED)*

2798

Treatment of partial epileptic seizures, primary generalised tonic-clonic epileptic seizures and seizures of the Lennox-Gastaut syndrome, which are not controlled satisfactorily by other anti-epileptic drugs in patients unable to take a solid dose form of topiramate

**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.

**topiramate 15 mg capsule, 60**

<table>
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<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>8371N</td>
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<td>5</td>
<td>18.40</td>
<td>19.55</td>
<td>Topamax Sprinkle [JC]</td>
</tr>
</tbody>
</table>

**topiramate 25 mg capsule, 60**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>8372P</td>
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<td>5</td>
<td>22.49</td>
<td>23.64</td>
<td>Topamax Sprinkle [JC]</td>
</tr>
</tbody>
</table>

**topiramate 50 mg capsule, 60**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>8520K</td>
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<td>5</td>
<td>32.98</td>
<td>34.13</td>
<td>Topamax Sprinkle [JC]</td>
</tr>
</tbody>
</table>

**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**

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.

---

**Topiramate 25 mg tablet, 60**

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Max Qty Packs</th>
<th>No of Rpts</th>
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<th>DPMO $</th>
<th>MRVSN $</th>
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<tbody>
<tr>
<td>APO-Topiramate [TX]</td>
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<td>23.90</td>
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<tr>
<td>Topiramate GH [GQ]</td>
<td></td>
<td>5</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Epiramax 25 [QA]</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Tamate [AF]</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Topiramate AN [EA]</td>
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<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Topiramate Sandoz [SZ]</td>
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**Topiramate 50 mg tablet, 60**

<table>
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<th>No of Rpts</th>
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<th>DPMO $</th>
<th>MRVSN $</th>
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<tbody>
<tr>
<td>APO-Topiramate [TX]</td>
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<td>34.18</td>
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<td>Topiramate GH [GQ]</td>
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<td>5</td>
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<td>Epiramax 50 [QA]</td>
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<tr>
<td>Tamate [AF]</td>
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<td>Topiramate AN [EA]</td>
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<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Topiramate Sandoz [SZ]</td>
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</tbody>
</table>

---

**Zonisamide**

**Authority required (STREAMLINED)**

2664

Treatment of partial epileptic seizures which are not controlled satisfactorily by other anti-epileptic drugs.

**Note**

Continuing Therapy Only:

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

---

**Zonisamide 100 mg capsule, 56**

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Max Qty Packs</th>
<th>No of Rpts</th>
<th>Premium $</th>
<th>DPMO $</th>
<th>MRVSN $</th>
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<tbody>
<tr>
<td>Zonegran [SA]</td>
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<td>2</td>
<td>93.80</td>
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**Zonisamide 25 mg capsule, 56**

<table>
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<th>No of Rpts</th>
<th>Premium $</th>
<th>DPMO $</th>
<th>MRVSN $</th>
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</thead>
<tbody>
<tr>
<td>Zonegran [SA]</td>
<td>9388D</td>
<td>1</td>
<td>23.14</td>
<td>24.29</td>
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**Zonisamide 50 mg capsule, 56**

<table>
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<th>No of Rpts</th>
<th>Premium $</th>
<th>DPMO $</th>
<th>MRVSN $</th>
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<tbody>
<tr>
<td>Zonegran [SA]</td>
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**Anti-Parkinson Drugs**

**Anticholinergic Agents**

**Tertiary amines**

---

**Benzhexol**

**Benzhexol hydrochloride 2 mg tablet, 200**

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Max Qty Packs</th>
<th>No of Rpts</th>
<th>Premium $</th>
<th>DPMO $</th>
<th>MRVSN $</th>
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<tbody>
<tr>
<td>Artane [QA]</td>
<td>1109J</td>
<td>1</td>
<td>15.66</td>
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**Benzhexol hydrochloride 5 mg tablet, 200**

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<th>No of Rpts</th>
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<th>MRVSN $</th>
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</thead>
<tbody>
<tr>
<td>Artane [QA]</td>
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<td>1</td>
<td>22.35</td>
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**Biperiden**

**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.

**Biphenyl hydrochloride 2 mg tablet, 100**

<table>
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<tr>
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<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>2544X</td>
<td>2</td>
<td>.</td>
<td>21.22</td>
<td>22.37</td>
<td>Akineton [LM]</td>
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**Ethers of tropine or tropine derivatives**

**Benztpine**

**Benztpine mesylate 2 mg tablet, 60**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
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<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>2362H</td>
<td>1</td>
<td>15.47</td>
<td>16.62</td>
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<td>Benztp [PL]</td>
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</tbody>
</table>

**Benztpine mesylate 2 mg/2 mL injection, 5 x 2 mL ampoules**

<table>
<thead>
<tr>
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<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>3038X</td>
<td>1</td>
<td>103.93</td>
<td>37.70</td>
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<td>Cogentin [FK]</td>
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</table>

**Dopamineergic agents**

**Dopa and dopa derivatives**

**Levodopa + Benzerazide**

**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.

**Levodopa with Benzerazide Dispersible tablet 100 mg-25 mg, 100**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>8219N</td>
<td>1</td>
<td>39.26</td>
<td>37.70</td>
<td></td>
<td>Madopar Rapid 125 [RO]</td>
</tr>
</tbody>
</table>

**Levodopa with Benzerazide Dispersible tablet 50 mg-12.5 mg, 100**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>8218M</td>
<td>1</td>
<td>39.26</td>
<td>37.70</td>
<td></td>
<td>Madopar Rapid 62.5 [RO]</td>
</tr>
</tbody>
</table>

**Levodopa 100 mg + benzerazide 25 mg capsule, 100**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>2225D</td>
<td>1</td>
<td>39.26</td>
<td>37.70</td>
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<td>Madopar 125 [RO]</td>
</tr>
</tbody>
</table>

**Levodopa 100 mg + benzerazide 25 mg capsule: modified release, 100 capsules**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>2231K</td>
<td>1</td>
<td>42.34</td>
<td>37.70</td>
<td></td>
<td>Madopar HBS [RO]</td>
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</tbody>
</table>

**Levodopa 100 mg + benzerazide 25 mg tablet, 100**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>2229H</td>
<td>1</td>
<td>39.26</td>
<td>37.70</td>
<td></td>
<td>Madopar 125 [RO]</td>
</tr>
</tbody>
</table>

**Levodopa 200 mg + benzerazide 50 mg capsule, 100**

<table>
<thead>
<tr>
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<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>2226E</td>
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<td>50.35</td>
<td>37.70</td>
<td></td>
<td>Madopar [RO]</td>
</tr>
</tbody>
</table>

**Levodopa 200 mg + benzerazide 50 mg tablet, 100**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
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<tbody>
<tr>
<td>2228G</td>
<td>1</td>
<td>50.35</td>
<td>37.70</td>
<td></td>
<td>Madopar [RO]</td>
</tr>
</tbody>
</table>

**Levodopa 50 mg + benzerazide 12.5 mg capsule, 100**

<table>
<thead>
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<th>No. of Rpts</th>
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<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>2227F</td>
<td>1</td>
<td>23.34</td>
<td>24.49</td>
<td></td>
<td>Madopar 62.5 [RO]</td>
</tr>
</tbody>
</table>
### LEVODOPA + CARBIDOPA ANHYDROUS

**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.

| levodopa 100 mg + carbidopa anhydrous 25 mg tablet, 100 |
|---|---|---|---|---|---|---|
| Max Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
| 1242J | 5 | .. | 38.63 | 37.70 | Kinson [AF] |
| 1245M | 5 | .. | 45.43 | 37.70 | Sinemet [MK] |

**LEVODOPA + CARBIDOPA ANHYDROUS**

**Authority required (STREAMLINED)**

1257
Parkinson’s disease where fluctuations in motor function are not adequately controlled by frequent dosing with conventional formulations of levodopa with decarboxylase inhibitor

**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.

| levodopa 200 mg + carbidopa anhydrous 50 mg tablet: modified release, 100 tablets |
|---|---|---|---|---|---|---|
| Max Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
| 1255C | 5 | .. | 68.21 | 37.70 | Sinemet CR [MK] |

### LEVODOPA + CARBIDOPA ANHYDROUS + ENTACAPONE

**Authority required (STREAMLINED)**

3305
Parkinson disease in patients being treated with levodopa—decarboxylase inhibitor combinations who are experiencing fluctuations in motor function due to end-of-dose effect

**Authority required (STREAMLINED)**

3306
Parkinson disease in patients stabilised on concomitant treatment with levodopa—decarboxylase inhibitor combinations and entacapone

**Note**
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.

| levodopa 100 mg + carbidopa anhydrous 25 mg + entacapone 200 mg tablet, 100 |
|---|---|---|---|---|---|---|
| Max Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
| 8798C | 4 | .. | *342.26 | 37.70 | Stalevo 100/25/200mg [NV] |
NERVOUS SYSTEM

levodopa 125 mg + carbidopa anhydrous 31.25 mg + entacapone 200 mg tablet, 100

<table>
<thead>
<tr>
<th>Max Qty</th>
<th>Packs</th>
<th>No of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tr>
<td>9345W</td>
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<td>354.30</td>
<td>37.70</td>
<td>Stalevo 125/31.25/200mg [NV]</td>
</tr>
</tbody>
</table>

levodopa 150 mg + carbidopa anhydrous 37.5 mg + entacapone 200 mg tablet, 100

<table>
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<th>Packs</th>
<th>No of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
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<td>4</td>
<td>..</td>
<td>372.30</td>
<td>37.70</td>
<td>Stalevo 150/37.5/200mg [NV]</td>
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</table>

levodopa 200 mg + carbidopa anhydrous 50 mg + entacapone 200 mg tablet, 100

<table>
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<th>Packs</th>
<th>No of Rpts</th>
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<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tr>
<td>9292C</td>
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<td>399.96</td>
<td>37.70</td>
<td>Stalevo 200/50/200mg [NV]</td>
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levodopa 50 mg + carbidopa anhydrous 12.5 mg + entacapone 200 mg tablet, 100

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<th>DPMQ $</th>
<th>MRVSN $</th>
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<td>4</td>
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<td>312.22</td>
<td>37.70</td>
<td>Stalevo 50/12.5/200mg [NV]</td>
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levodopa 75 mg + carbidopa anhydrous 18.75 mg + entacapone 200 mg tablet, 100

<table>
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<th>Packs</th>
<th>No of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<td>9344T</td>
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<td>4</td>
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<td>325.46</td>
<td>37.70</td>
<td>Stalevo 75/18.75/200mg [NV]</td>
</tr>
</tbody>
</table>

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.

amantadine hydrochloride 100 mg capsule, 100

<table>
<thead>
<tr>
<th>Max Qty</th>
<th>Packs</th>
<th>No of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
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<tr>
<td>3016R</td>
<td>1</td>
<td>5</td>
<td>..</td>
<td>44.64</td>
<td>37.70</td>
<td>Symmetrel 100 [NV]</td>
</tr>
</tbody>
</table>

Dopamine agonists

BROMOCRIPTINE

Restricted benefit
Acromegaly
Restricted benefit
Parkinson’s disease
Restricted benefit
Pathological hyperprolactinaemia where surgery is not indicated
Restricted benefit
Pathological hyperprolactinaemia where surgery has already been used with incomplete resolution
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.

bromocriptine 2.5 mg tablet, 30

<table>
<thead>
<tr>
<th>Max Qty</th>
<th>Packs</th>
<th>No of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
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<tbody>
<tr>
<td>1443Y</td>
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<td>..</td>
<td>31.76</td>
<td>32.91</td>
<td>Parlodel [NV]</td>
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bromocriptine 2.5 mg tablet, 60

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<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>1559C</td>
<td>1</td>
<td>5</td>
<td>..</td>
<td>31.76</td>
<td>32.91</td>
<td>Kripton 2.5 [AF]</td>
</tr>
</tbody>
</table>

CABERGOLINE

Restricted benefit
Parkinson's disease

Note
Care should be taken when treating patients with advanced age and significant cognitive impairment with dopamine agonists.

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.

cabergoline 1 mg tablet, 30

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>* Cabaser [PF]</td>
<td>* Cobasol [GN]</td>
</tr>
</tbody>
</table>

pramipexole hydrochloride monohydrate 1 mg tablet, 100

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>* APO-Pramipexole [TX]</td>
<td>* Sifrol [BY]</td>
</tr>
<tr>
<td>* Pramipexole GH [GQ]</td>
<td>* Simipex 1 [QA]</td>
</tr>
</tbody>
</table>

pramipexole hydrochloride monohydrate 125 microgram tablet, 30

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>* APO-Pramipexole [TX]</td>
<td>* Sifrol [BY]</td>
</tr>
<tr>
<td>* Pramipexole GH [GQ]</td>
<td>* Simipex 0.125 [QA]</td>
</tr>
</tbody>
</table>

pramipexole hydrochloride monohydrate 250 microgram tablet, 100

<table>
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<tr>
<th>Brand Name and Manufacturer</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>* APO-Pramipexole [TX]</td>
<td>* Sifrol [BY]</td>
</tr>
<tr>
<td>* Pramipexole GH [GQ]</td>
<td>* Simipex 0.25 [QA]</td>
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</tbody>
</table>

● PRAMIPEXOLE

Caution
Episodes of sudden onset of sleep without warning, during activity, have been reported with this drug.

Restricted benefit
Parkinson disease

Note
Care should be taken when treating patients with advanced age and significant cognitive impairment with dopamine agonists.

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

pramipexole hydrochloride monohydrate 1.5 mg tablet: modified release, 30 tablets

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sifrol ER [BY]</td>
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</table>
pramipexole hydrochloride monohydrate 2.25 mg tablet: modified release, 30 tablets  
5143Q

<table>
<thead>
<tr>
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<th>No of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
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<tbody>
<tr>
<td>1</td>
<td>5</td>
<td>..</td>
<td>82.50</td>
<td>37.70</td>
<td>Sifrol ER [BY]</td>
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</tbody>
</table>

pramipexole hydrochloride monohydrate 3 mg tablet: modified release, 30 tablets  
3421C

<table>
<thead>
<tr>
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<th>No of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>5</td>
<td>..</td>
<td>116.91</td>
<td>37.70</td>
<td>Sifrol ER [BY]</td>
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pramipexole hydrochloride monohydrate 3.75 mg tablet: modified release, 30 tablets  
5145T

<table>
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<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>5</td>
<td>..</td>
<td>142.16</td>
<td>37.70</td>
<td>Sifrol ER [BY]</td>
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pramipexole hydrochloride monohydrate 375 microgram tablet: modified release, 30 tablets  
3418X

<table>
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<th>DPMQ $</th>
<th>MRVSN $</th>
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<tbody>
<tr>
<td>1</td>
<td>5</td>
<td>..</td>
<td>20.18</td>
<td>21.33</td>
<td>Sifrol ER [BY]</td>
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pramipexole hydrochloride monohydrate 4.5 mg tablet: modified release, 30 tablets  
3422D

<table>
<thead>
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<th>MRVSN $</th>
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<tr>
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<td>172.00</td>
<td>37.70</td>
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pramipexole hydrochloride monohydrate 750 microgram tablet: modified release, 30 tablets  
3419Y

<table>
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<th>DPMQ $</th>
<th>MRVSN $</th>
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<tbody>
<tr>
<td>1</td>
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<td>..</td>
<td>33.14</td>
<td>34.29</td>
<td>Sifrol ER [BY]</td>
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</table>

**PRAMIPEXOLE**

**Caution**  
Episodes of sudden onset of sleep without warning, during activity, have been reported with this drug.

**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.

**Note**  
Care should be taken when treating patients with advanced age and significant cognitive impairment with dopamine agonists.

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

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

pramipexole hydrochloride monohydrate 125 microgram tablet, 30  
9393J

<table>
<thead>
<tr>
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<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>1</td>
<td>2</td>
<td>..</td>
<td>11.23</td>
<td>12.38</td>
<td>Sifrol [BY]</td>
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pramipexole hydrochloride monohydrate 250 microgram tablet, 100  
9394K

<table>
<thead>
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<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>1</td>
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<td>..</td>
<td>36.07</td>
<td>37.22</td>
<td>Sifrol [BY]</td>
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</table>

**ROTIGOTINE**

**Restricted benefit**  
Parkinson disease

**Clinical criteria:**  
The treatment must be as adjunctive therapy to a levodopa-decarboxylase inhibitor combination.
rotigotine 4 mg/24 hours patch, 28

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMO $</th>
<th>MRVSN $</th>
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<td>Neupro [UC]</td>
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rotigotine 6 mg/24 hours patch, 28

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMO $</th>
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<td>Neupro [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.

rotigotine 2 mg/24 hours patch, 28

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
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<th>MRVSN $</th>
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</table>

*Monoamine oxidase B inhibitors*

**RASAGILINE**

**Authority required (STREAMLINED)**

**4053**

**Parkinson disease**

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

RASAGILINE Tablet 1 mg (as mesilate), 30

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMO $</th>
<th>MRVSN $</th>
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<td></td>
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<td></td>
<td>Azilect [LU]</td>
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</tr>
</tbody>
</table>

**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.

selegiline hydrochloride 5 mg tablet, 100

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMO $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>*Eldepryl [AS]</td>
<td>*Selgene [AF]</td>
</tr>
</tbody>
</table>

*Other dopaminergic agents*

**ENTACAPONE**

**Authority required (STREAMLINED)**

**2067**

Parkinson's disease as adjunctive therapy in patients being treated with levodopa—decarboxylase inhibitor combinations who are experiencing fluctuations in motor function due to end-of-dose effect

**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.

entacapone 200 mg tablet, 100

<table>
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<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMO $</th>
<th>MRVSN $</th>
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<td>8367J</td>
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<td></td>
<td>*282.16</td>
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</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Comtan [NV]</td>
<td></td>
</tr>
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</table>

**PSYCHOLEPTICS**

**ANTIPSYCHOTICS**

**Phenothiazines with aliphatic side-chain**
### CHLORPROMAZINE

**Note**

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

<table>
<thead>
<tr>
<th>Chlorpromazine Hydrochloride 10 mg Tablet, 100</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1196Y</strong></td>
</tr>
<tr>
<td></td>
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</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Chlorpromazine Hydrochloride 100 mg Tablet, 100</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1199D</strong></td>
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<tr>
<td></td>
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</table>

<table>
<thead>
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<tr>
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</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Chlorpromazine Hydrochloride 5 mg/mL Oral Liquid, 100 mL</th>
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</thead>
<tbody>
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<table>
<thead>
<tr>
<th>Chlorpromazine Hydrochloride 50 mg/2 mL Injection, 10 x 2 mL Ampoules</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1195X</strong></td>
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</tbody>
</table>

### FLUPHENAZINE DECANOATE

**Note**

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

<table>
<thead>
<tr>
<th>Fluphenazine Decanoate 12.5 mg/0.5 mL Injection, 5 x 0.5 mL Ampoules</th>
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</thead>
<tbody>
<tr>
<td><strong>1046C</strong></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Fluphenazine Decanoate 25 mg/mL Injection, 5 x 1 mL Ampoules</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>3098C</strong></td>
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<tr>
<td></td>
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</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Fluphenazine Decanoate 50 mg/2 mL Injection, 5 x 2 mL Ampoules</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1001Q</strong></td>
</tr>
<tr>
<td></td>
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</tr>
</tbody>
</table>

### TRIFLUOPERAZINE

**Note**

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

<table>
<thead>
<tr>
<th>Trifluoperazine 1 mg Tablet, 100</th>
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</thead>
<tbody>
<tr>
<td><strong>2185B</strong></td>
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<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Trifluoperazine 2 mg Tablet, 100</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>2386N</strong></td>
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<td></td>
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<td></td>
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<tr>
<td></td>
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<tr>
<td></td>
</tr>
</tbody>
</table>
**NERVOUS SYSTEM**

**PERICYAZINE**

*Note*

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

**PERICYAZINE**

- pericyazine 10 mg tablet, 100
- pericyazine 2.5 mg tablet, 100

**HALOPERIDOL**

*Note*

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

**HALOPERIDOL**

- haloperidol 1.5 mg tablet, 100
- haloperidol 2 mg/mL oral liquid, 100 mL
- haloperidol 5 mg tablet, 50
- haloperidol 5 mg/mL injection, 10 x 1 mL ampoules
- haloperidol 500 microgram tablet, 100

**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.

**HALOPERIDOL DECANOATE**

- haloperidol (as decanoate) 150 mg/3 mL injection, 5 x 3 mL ampoules
- haloperidol (as decanoate) 50 mg/mL injection, 5 x 1 mL vials

**Indole derivatives**
**NERVOUS SYSTEM**

### ZIPRASIDONE

**Authority required (STREAMLINED)**

1. **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.

#### ziprasidone 20 mg capsule, 60

<table>
<thead>
<tr>
<th></th>
<th>Max.Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>9070J</td>
<td>1</td>
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<td>66.05</td>
<td>37.70</td>
<td>* APO-Ziprasidone [TX]</td>
<td>* Zeldox [PF]</td>
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</table>

#### ziprasidone 40 mg capsule, 60

<table>
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<th></th>
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<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
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<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
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<td>9071K</td>
<td>1</td>
<td>5</td>
<td>..</td>
<td>125.54</td>
<td>37.70</td>
<td>* APO-Ziprasidone [TX]</td>
<td>* Zeldox [PF]</td>
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#### ziprasidone 60 mg capsule, 60

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<th>DPMQ $</th>
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<th>Brand Name and Manufacturer</th>
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<td>9072L</td>
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<td>5</td>
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<td>184.30</td>
<td>37.70</td>
<td>* APO-Ziprasidone [TX]</td>
<td>* Zeldox [PF]</td>
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#### ziprasidone 80 mg capsule, 60

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<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
<th>Brand Name and Manufacturer</th>
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<td>9073M</td>
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<td>240.24</td>
<td>37.70</td>
<td>* APO-Ziprasidone [TX]</td>
<td>* Zeldox [PF]</td>
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</table>

### FLUPENTHIXOL DECANOATE

**Note**

Shared Care Model:

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

#### flupenthixol decanoate 100 mg/mL injection, 5 x 1 mL ampoules

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<th>Max.Qty Packs</th>
<th>No. of Rpts</th>
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<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>2257T</td>
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<td>..</td>
<td>48.61</td>
<td>37.70</td>
<td>Fluanxol Concentrated Depot [LU]</td>
</tr>
</tbody>
</table>

#### flupenthixol decanoate 20 mg/mL injection, 5 x 1 mL ampoules

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<th></th>
<th>Max.Qty Packs</th>
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<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<td>20.85</td>
<td>22.00</td>
<td>Fluanxol Depot [LU]</td>
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</tbody>
</table>

### ZUCLOPENTHIXOL DECANOATE

**Note**

Shared Care Model:

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

#### zuclopenthixol decanoate 200 mg/mL injection, 5 x 1 mL ampoules

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<th>Max.Qty Packs</th>
<th>No. of Rpts</th>
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<tr>
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<td>..</td>
<td>27.58</td>
<td>28.73</td>
<td>Clopixol Depot [LU]</td>
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</tbody>
</table>

### Diazepines, oxazepines, thiazepines and oxepines

#### ASENAPINE

**Authority required (STREAMLINED)**

1. **1589**
   - Schizophrenia
   - **Authority required (STREAMLINED)**
   - **3935**
   - Treatment, for up to 6 months, of an episode of acute mania or mixed episodes associated with bipolar I disorder
NERVOUS SYSTEM

**Authority required (STREAMLINED)**

3936

Maintenance treatment, as monotherapy, of bipolar I disorder

**Note**

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

**asenapine 10 mg wafer: sublingual, 60 wafers**

<table>
<thead>
<tr>
<th>5141N</th>
<th>Max.Qty</th>
<th>Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>5</td>
<td>..</td>
<td>253.06</td>
<td>37.70</td>
<td>Saphris [LU]</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**asenapine 5 mg wafer: sublingual, 60 wafers**

<table>
<thead>
<tr>
<th>5140M</th>
<th>Max.Qty</th>
<th>Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>5</td>
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<td>157.41</td>
<td>37.70</td>
<td>Saphris [LU]</td>
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</table>

**OLANZAPINE**

**Authority required (STREAMLINED)**

1589

Schizophrenia

**Authority required (STREAMLINED)**

2044

Maintenance treatment of bipolar I disorder

**Note**

Pharmaceutical benefits that have the form olanzapine tablet 2.5 mg and pharmaceutical benefits that have the form olanzapine tablet 2.5 mg (as benzoate) are equivalent for the purposes of substitution.

**olanzapine 2.5 mg tablet, 28**

<table>
<thead>
<tr>
<th>1024X</th>
<th>Max.Qty</th>
<th>Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>1</td>
<td>5</td>
<td>..</td>
<td>17.19</td>
<td>18.34</td>
<td>* Olanzapine generichealth 2.5 [GQ]</td>
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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 and pharmaceutical benefits that have the form olanzapine tablet 5 mg (as benzoate) are equivalent for the purposes of substitution.

**olanzapine 5 mg tablet, 28**

<table>
<thead>
<tr>
<th>1037N</th>
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<th>Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>1</td>
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<td>..</td>
<td>27.43</td>
<td>28.58</td>
<td>* Olanzapine generichealth 5 [GQ]</td>
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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 7.5 mg and pharmaceutical benefits that have the form olanzapine tablet 7.5 mg (as benzoate) are equivalent for the purposes of substitution.

**olanzapine 7.5 mg tablet, 28**

<table>
<thead>
<tr>
<th>1041T</th>
<th>Max.Qty</th>
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<th>No. of Rpts</th>
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<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>5</td>
<td>..</td>
<td>38.06</td>
<td>37.70</td>
<td>* Olanzapine generichealth 7.5 [GQ]</td>
<td></td>
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</table>
OLANZAPINE

Authority required (STREAMLINED)

1589
Schizophrenia

Authority required (STREAMLINED)

2044
Maintenance treatment of bipolar I disorder

Note
Pharmaceutical benefits that have the form olanzapine tablet 10 mg and pharmaceutical benefits that have the form olanzapine tablet 10 mg (as benzoate) are equivalent for the purposes of substitution.

Olanzapine 10 mg tablet, 28

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Olanzapine generichealth 10 [GQ]</td>
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</table>

OLANZAPINE Tablet 5 mg (orally disintegrating), 28

<table>
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<th>Max Qty Packs</th>
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<th>Premium $</th>
<th>DPMQ $</th>
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<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* APO-Olanzapine ODT [TX]</td>
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<td></td>
<td>* Olanzapine AN ODT [EA]</td>
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<td></td>
<td>* Olanzapine ODT-DRLA [RZ]</td>
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<td>* Olanzapine RBX ODT [RA]</td>
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<td></td>
<td></td>
<td>* Pharmacy Choice Olanzapine ODT [RI]</td>
</tr>
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<td></td>
<td></td>
<td></td>
<td>* Chem mart Olanzapine ODT [CH]</td>
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<td></td>
<td>* Olanzapine-GA ODT [GN]</td>
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<td>* Olanzapine ODT generichealth 5 [GQ]</td>
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<td></td>
<td></td>
<td>* Olanzapine Sandoz ODT 5 [SZ]</td>
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<td>* Terry White Chemists Olanzapine ODT [TW]</td>
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</table>

OLANZAPINE Tablet 10 mg (orally disintegrating), 28

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td></td>
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<td></td>
<td></td>
<td></td>
<td>* APO-Olanzapine ODT [TX]</td>
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<td></td>
<td>* Olanzapine AN ODT [EA]</td>
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<td></td>
<td>* Olanzapine ODT-DRLA [RZ]</td>
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<td>* Olanzapine RBX ODT [RA]</td>
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<td></td>
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<td></td>
<td>* Pharmacy Choice Olanzapine ODT [RI]</td>
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<td></td>
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<td>* Chem mart Olanzapine ODT [CH]</td>
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<td></td>
<td></td>
<td>* Olanzapine-GA ODT [GN]</td>
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<td></td>
<td></td>
<td></td>
<td>* Olanzapine ODT generichealth 10 [GQ]</td>
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<td></td>
<td></td>
<td></td>
<td>* Olanzapine Sandoz ODT 10 [SZ]</td>
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<td></td>
<td></td>
<td></td>
<td>* Terry White Chemists Olanzapine ODT [TW]</td>
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</table>
Maintenance treatment of bipolar I disorder

**Note**
Pharmaceutical benefits that have the form olanzapine tablet 15 mg (orally disintegrating) and pharmaceutical benefits that have the form olanzapine wafer 15 mg are equivalent for the purposes of substitution.

<table>
<thead>
<tr>
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<tbody>
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**OLANZAPINE**

**Authority required (STREAMLINED)**
1589
Schizophrenia

**Authority required (STREAMLINED)**
2044
Maintenance treatment of bipolar I disorder

**Note**
Pharmaceutical benefits that have the form olanzapine tablet 20 mg (orally disintegrating) and pharmaceutical benefits that have the form olanzapine wafer 20 mg are equivalent for the purposes of substitution.

<table>
<thead>
<tr>
<th>olanzapine 20 mg tablet, 28</th>
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<td>Max Qty Packs</td>
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**OLANZAPINE**

**Authority required (STREAMLINED)**
1589
Schizophrenia

**Authority required (STREAMLINED)**
2044
Maintenance treatment of bipolar I disorder

**Note**
Pharmaceutical benefits that have the form olanzapine tablet 2.5 mg and pharmaceutical benefits that have the form olanzapine tablet 2.5 mg (as benzoate) are equivalent for the purposes of substitution.

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

<table>
<thead>
<tr>
<th>olanzapine 2.5 mg tablet, 28</th>
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</thead>
<tbody>
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</table>

**OLANZAPINE**

**Authority required (STREAMLINED)**
1589
Schizophrenia

**Authority required (STREAMLINED)**
2044
Maintenance treatment of bipolar I disorder

**Note**
Pharmaceutical benefits that have the form olanzapine tablet 5 mg and pharmaceutical benefits that have the form olanzapine tablet 5 mg (as benzoate) are equivalent for the purposes of substitution.
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 5 mg tablet, 28

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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 7.5 mg and pharmaceutical benefits that have the form olanzapine tablet 7.5 mg (as benzoate) are equivalent for the purposes of substitution.

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 7.5 mg tablet, 28

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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 10 mg and pharmaceutical benefits that have the form olanzapine tablet 10 mg (as benzoate) are equivalent for the purposes of substitution.

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 10 mg tablet, 28

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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 5 mg (orally disintegrating) and pharmaceutical benefits that have the form olanzapine wafer 5 mg are equivalent for the purposes of substitution.

  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 5 mg wafer, 28**

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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 10 mg (orally disintegrating) and pharmaceutical benefits that have the form olanzapine wafer 10 mg are equivalent for the purposes of substitution.

  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 10 mg wafer, 28**

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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 15 mg (orally disintegrating) and pharmaceutical benefits that have the form olanzapine wafer 15 mg are equivalent for the purposes of substitution.

  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 15 mg wafer, 28**

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1589
Schizophrenia

**Authority required (STREAMLINED)**

2044
Maintenance treatment of bipolar I disorder

**Note**
Pharmaceutical benefits that have the form olanzapine tablet 20 mg (orally disintegrating) and pharmaceutical benefits that have the form olanzapine wafer 20 mg are equivalent for the purposes of substitution.

**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

**Caution**
Monitor for post-injection syndrome for at least two hours after each injection.

**Authority required (STREAMLINED)**

4304
Schizophrenia

**Note**
Special Pricing Arrangements apply.

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

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### 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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### NERVOUS SYSTEM

#### Quetiapine 150 mg tablet: modified release, 60 tablets

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#### Quetiapine 200 mg tablet, 60

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#### Quetiapine 300 mg tablet: modified release, 60 tablets

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#### Quetiapine 300 mg tablet, 60

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#### Quetiapine 400 mg tablet: modified release, 60 tablets

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#### Quetiapine 50 mg tablet: modified release, 60 tablets

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### QUETIAPINE

**Authority required (STREAMLINED)**

4391

Schizophrenia

**Clinical criteria:**
The treatment must be for dose titration purposes.

**Authority required (STREAMLINED)**
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)

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.
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.

quetiapine 25 mg tablet, 60

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Benzamides

AMISULPRIDE

Authority required (STREAMLINED)

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.

amisulpride 100 mg tablet, 30

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amisulpride 100 mg/mL oral liquid, 60 mL

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amisulpride 200 mg tablet, 60

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<th>MRVSN $</th>
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<th>Brand Name and Manufacturer</th>
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<td>Amisulpride Sandoz [SZ]</td>
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**NERVOUS SYSTEM**

**amisulpride 400 mg tablet, 60**

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**Other antipsychotics**

- **ARIPIPRAZOLE**
  - **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.

  **aripiprazole 300 mg injection: modified release [1 x 300 mg vial] (&) inert substance diluent [1 vial], 1 pack**

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  **aripiprazole 400 mg injection: modified release [1 x 400 mg vial] (&) inert substance diluent [1 vial], 1 pack**

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<th>No. of Rpts</th>
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<th>Brand Name and Manufacturer</th>
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- **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.

  **aripiprazole 10 mg tablet, 30**

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  **aripiprazole 15 mg tablet, 30**

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  **aripiprazole 30 mg tablet, 30**

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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.
### NERVOUS SYSTEM

#### 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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#### Risperidone 2 mg tablet, 60

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#### Risperidone 2 mg tablet: orally disintegrating, 28

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<th>Risperdal Quicklet [JC]</th>
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#### Paliperidone 100 mg injection: modified release, 1 syringe

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#### Paliperidone 150 mg injection: modified release, 1 syringe

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#### Paliperidone 25 mg injection: modified release, 1 syringe

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#### Paliperidone 3 mg tablet: modified release, 28 tablets

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#### Paliperidone 50 mg injection: modified release, 1 syringe

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#### Paliperidone 6 mg tablet: modified release, 28 tablets

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#### Paliperidone 75 mg injection: modified release, 1 syringe

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#### Paliperidone 9 mg tablet: modified release, 28 tablets

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NERVOUS SYSTEM

- **Risperidone**
  - Authority required (STREAMLINED)
  - 1589
  - Schizophrenia

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

  **risperidone 500 microgram tablet: orally disintegrating, 28**

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  **risperidone 1 mg tablet, 60**

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<td>Risperidone Sandoz [SZ]</td>
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<td>Rixadone [AF]</td>
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  **risperidone 1 mg/mL oral liquid, 100 mL**

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  **risperidone 2 mg tablet, 60**

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<td>Risperidone-GA [GN]</td>
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<td>Risperidone Sandoz [SZ]</td>
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  **risperidone 2 mg tablet: orally disintegrating, 28**

<table>
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  **risperidone 3 mg tablet, 60**

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### NERVOUS SYSTEM

**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**

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

---

**Risperidone 3 mg tablet: orally disintegrating, 28**

<table>
<thead>
<tr>
<th>Code</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>9075P</td>
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<td>..</td>
<td>*51.10</td>
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<td>Risperdal Quicklet [JC]</td>
</tr>
</tbody>
</table>

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**Risperidone 4 mg tablet, 60**

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<td>37.70</td>
<td>APO-Risperidone [TX]</td>
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**Risperidone 4 mg tablet: orally disintegrating, 28**

<table>
<thead>
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<th>Brand Name and Manufacturer</th>
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**Risperidone 25 mg injection: modified release [1 x 25 mg vial] (&) inert substance diluent [1 x 2 mL syringe], 1 pack**

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<tr>
<th>Code</th>
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<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
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**Risperidone 37.5 mg injection: modified release [1 x 37.5 mg vial] (&) inert substance diluent [1 x 2 mL syringe], 1 pack**

<table>
<thead>
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<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>8781E</td>
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<td>5</td>
<td>..</td>
<td>*353.78</td>
<td>37.70</td>
<td>Risperdal Consta [JC]</td>
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**Risperidone 50 mg injection: modified release [1 x 50 mg vial] (&) inert substance diluent [1 x 2 mL syringe], 1 pack**

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<th>DPMQ $</th>
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**Risperidone 500 microgram tablet, 20**

<table>
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<th>No. of Rpts</th>
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<th>DPMQ $</th>
<th>MRVSN $</th>
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<td>14.78</td>
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</tbody>
</table>

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Note:

For item codes 8869T and 1846E, pharmaceutical benefits that have the form tablet 0.5 mg are equivalent for the purposes of substitution.

**Shared Care Model:**

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

### 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.

**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

### Note

**Shared Care Model:**

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

---

### risperidone 500 microgram tablet, 60

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>Ozidal [RA]</td>
<td>Rispa [QA]</td>
</tr>
<tr>
<td>Risperidone 0.5 [CR]</td>
<td>Risperidone Actavis 0.5 [UA]</td>
</tr>
<tr>
<td>Risperidone AN [EA]</td>
<td>Risperidone-DRLA [RZ]</td>
</tr>
<tr>
<td>Risperidone-GA [GN]</td>
<td>Risperidone GH [GQ]</td>
</tr>
<tr>
<td>Risperidone Sandoz [SZ]</td>
<td>Rispernia [ER]</td>
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<td>Rixadone [AF]</td>
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### risperidone 1 mg tablet, 60

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
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<td>APO-Risperidone [TX]</td>
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<td>Rispa [QA]</td>
<td>Risperidone Actavis 1 [UA]</td>
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<tr>
<td>Risperidone 1 [CR]</td>
<td>Risperidone-DRLA [RZ]</td>
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<tr>
<td>Risperidone AN [EA]</td>
<td>Risperidone generichealth [GQ]</td>
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<tr>
<td>Risperidone-GA [GN]</td>
<td>Rispernia [ER]</td>
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<tr>
<td>Risperidone Sandoz [SZ]</td>
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<td>Rixadone [AF]</td>
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### risperidone 1 mg tablet: orally disintegrating, 28

<table>
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<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
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<td>Risperdal Quicklet [JC]</td>
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### risperidone 1 mg/mL oral liquid, 100 mL

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### risperidone 500 microgram tablet: orally disintegrating, 28

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Risperdal Quicklet [JC]</td>
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</tbody>
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### RISPERIDONE

### 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.

**Authority required (STREAMLINED)**

2061

Behavioural disturbances characterised by psychotic symptoms and aggression in patients with dementia where non-pharmacological methods have been unsuccessful
NERVOUS SYSTEM

Schedule of Pharmaceutical Benefits

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
For item codes 8787L and 1842Y, pharmaceutical benefits that have the form tablet 0.5 mg are equivalent for the purposes of substitution.

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.

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

ANXIOLYTICS

Benzodiazepine derivatives

ALPRAZOLAM

Authority required
Panic disorder where other treatments have failed or are inappropriate

risperidone 500 microgram tablet, 20

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<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
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<th>Brand Name and Manufacturer</th>
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risperidone 500 microgram tablet, 60

<table>
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<td>Risperidone Actavis 0.5 [UA]</td>
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<td></td>
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<td></td>
<td>Rispercor 0.5 [CR]</td>
<td>Risperidone-DRLA [RZ]</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Risperidone AN [EA]</td>
<td>Risperidone GH [GQ]</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Risperidone-GA [GN]</td>
<td>Risperidone [JC]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Risperidone Sandoz [SZ]</td>
<td>Risperidone [JC]</td>
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<td>Rixadone [AF]</td>
<td>Risperidone [JC]</td>
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ALPRAZOLAM

Authority required
Panic disorder where other treatments have failed or are inappropriate

alprazolam 1 mg tablet, 50

<table>
<thead>
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<td>Chem mart Alprazolam [CH]</td>
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<td>GenRx Alprazolam [GX]</td>
<td>Kalma 1 [AF]</td>
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alprazolam 2 mg tablet, 50

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<td>GenRx Alprazolam [GX]</td>
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alprazolam 250 microgram tablet, 50

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<td>Kalma 0.25 [AF]</td>
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alprazolam 500 microgram tablet, 50

<table>
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<th>DPMQ $</th>
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<tbody>
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<td>2131E</td>
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<td>Kalma 0.5 [AF]</td>
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</table>

DIAZEPAM

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

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
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<tr>
<td>5073B</td>
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<td>13.68</td>
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<td>Hospira Pty Limited [HH]</td>
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</table>
NERVOUS SYSTEM

**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.

**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.
NERVOUS SYSTEM

oxazepam 15 mg tablet, 25

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Alepam 15 [AF]</td>
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<tr>
<td></td>
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<td>2.68</td>
<td>10.68</td>
<td>9.15</td>
<td>* Serepax [QA]</td>
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oxazepam 30 mg tablet, 25

<table>
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<th>No. of Rpts</th>
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<th>MRVSN $</th>
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<td>* Alepam 30 [AF]</td>
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<td>2.68</td>
<td>10.68</td>
<td>9.15</td>
<td>* Serepax [QA]</td>
</tr>
</tbody>
</table>

• OXAZEPAM

Authority required
Malignant neoplasia (late stage)

Authority required
For use by patients who are receiving long-term nursing care on account of age, infirmity or other condition in hospitals, nursing homes or residential facilities and who have been demonstrated, within the past 6 months, to be benzodiazepine dependent by an unsuccessful attempt at gradual withdrawal

Authority required
For use by a patient who is receiving long-term nursing care and in respect of whom a Carer Allowance is payable as a disabled adult and who has been demonstrated, within the past 6 months, to be benzodiazepine dependent by an unsuccessful attempt at gradual withdrawal

oxazepam 15 mg tablet, 25

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>2.68</td>
<td>10.68</td>
<td>9.15</td>
<td>* Serepax [QA]</td>
</tr>
</tbody>
</table>

oxazepam 30 mg tablet, 25

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
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<tbody>
<tr>
<td></td>
<td></td>
<td>5.36</td>
<td>14.60</td>
<td>10.39</td>
<td>* Serepax [QA]</td>
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</table>

HYPNOTICS AND SEDATIVES

Benzodiazepine derivatives

• NITRAZEPAM

nitrazepam 5 mg tablet, 25

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
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<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td></td>
<td></td>
<td>3.56</td>
<td>9.59</td>
<td>9.50</td>
<td>* Mogadon [IA]</td>
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</table>

• 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.

nitrazepam 5 mg tablet, 25

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
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<td>1.24</td>
<td>9.59</td>
<td>9.50</td>
<td>* Mogadon [IA]</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 and who have been demonstrated, within the past 6 months, to be benzodiazepine dependent by an unsuccessful attempt at gradual withdrawal

Authority required
For use by a patient who is receiving long-term nursing care and in respect of whom a Carer Allowance is payable as a disabled adult and who has been demonstrated, within the past 6 months, to be benzodiazepine dependent by an unsuccessful attempt at gradual withdrawal

Note
Continuing Therapy Only:
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.

### Nitrazepam 5 mg tablet, 25

<table>
<thead>
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<td>2732T</td>
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<td>9.94</td>
<td>11.09</td>
<td>* Alodorm [AF]</td>
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<td>2.48</td>
<td>12.42</td>
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</table>

### Temezepam

**Note**
Authorities for increased maximum quantities and/or repeats will not be granted except as detailed under the 'Authority required' listing of temazepam below.

#### Temazepam 10 mg tablet, 25

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<td></td>
<td></td>
<td></td>
<td>* Temaze [AF]</td>
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<td>* Temtabs [FM]</td>
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<td>4.00</td>
<td>11.69</td>
<td>* Normison [QA]</td>
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### Temezepam

**Authority required**
Malignant neoplasia (late stage)

**Authority required**
For use by patients who are receiving long-term nursing care on account of age, infirmity or other condition in hospitals, nursing homes or residential facilities and who have been demonstrated, within the past 6 months, to be benzodiazepine dependent by an unsuccessful attempt at gradual withdrawal

**Authority required**
For use by a patient who is receiving long-term nursing care and in respect of whom a Carer Allowance is payable as a disabled adult and who has been demonstrated, within the past 6 months, to be benzodiazepine dependent by an unsuccessful attempt at gradual withdrawal

**Note**
Continuing Therapy Only:
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.

#### Temazepam 10 mg tablet, 25

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<td>4.00</td>
<td>11.69</td>
<td>* Normison [QA]</td>
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### Temezepam

**Authority required**
Non-selective monoamine reuptake inhibitors

### Amitriptyline

**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.

#### Amitriptyline hydrochloride 10 mg tablet, 50

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<td>* Chem mart Amitriptyline [CH]</td>
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### NERVOUS SYSTEM

#### Amitriptyline Hydrochloride 25 mg tablet, 50

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#### Amitriptyline Hydrochloride 50 mg tablet, 50

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<td>* Endep 50 [AF]</td>
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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.

#### Clomipramine Hydrochloride 25 mg tablet, 50

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### Dothiepin

**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.

#### Dothiepin Hydrochloride 25 mg capsule, 50

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#### Dorthiepin Hydrochloride 75 mg tablet, 30

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### Doxepin

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

#### Doxepin 10 mg capsule, 50

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<td>13.12</td>
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#### Doxepin 25 mg capsule, 50

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<td>10.39</td>
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**NERVOUS SYSTEM**

**doxepin 50 mg tablet, 50**

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<td>11.36</td>
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**IMIPRAMINE**

**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.

**imipramine hydrochloride 10 mg tablet, 50**

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**imipramine hydrochloride 25 mg tablet, 50**

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<td>12.77</td>
<td>13.92</td>
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<td>2.78</td>
<td>15.55</td>
<td>13.92</td>
<td>* Tofranil 25 [LM]</td>
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</table>

**NORTRIPTYLINE**

**Restricted benefit**

Major depression where other antidepressant therapy has failed

**Restricted benefit**

Major depression where other antidepressant therapy is contraindicated

**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.

**nortriptyline 10 mg tablet, 50**

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<td>14.81</td>
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**nortriptyline 25 mg tablet, 50**

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**Selective serotonin reuptake inhibitors**

**CITALOPRAM**

**Restricted benefit**

Major depressive disorders

**citalopram 10 mg tablet, 28**

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<th>Max Qty Packs</th>
<th>No. of Rpts</th>
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<td>8.39</td>
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<td></td>
<td>* Citalopram-GA [GN]</td>
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<td>* Citalopram [AF]</td>
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**citalopram 20 mg tablet, 28**

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<td>* Celapram [AF]</td>
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<td>* Chem mart Citalopram [CH]</td>
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<td>* Citalopram-GA [GN]</td>
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<td>* Flamorph Citalopram 20 [CR]</td>
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**citalopram 40 mg tablet, 28**

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<td>* Celapram [AF]</td>
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</table>
ESCITALOPRAM

**Restricted benefit**

**Major depressive disorders**

escitalopram 10 mg tablet, 28

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<td>4.28</td>
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escitalopram 20 mg tablet, 28

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**ESCITALOPRAM**

**Restricted benefit**

**Moderate to severe generalised anxiety disorder (GAD)**

Clinical criteria:
The condition must be defined by Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) criteria, AND Patient must have been assessed by a psychiatrist.

Patient must be one for whom a GP Mental Health Care Plan, as described under items 2715 or 2717 of the Medicare Benefits Schedule, has been prepared.

**Restricted benefit**

**Moderate to severe generalised anxiety disorder (GAD)**

Clinical criteria:
The condition must be defined by Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) criteria, AND Patient must have been assessed by a psychiatrist.

Patient must be one for whom a GP Mental Health Care Plan, as described under items 2715 or 2717 of the Medicare Benefits Schedule, has been prepared.

escitalopram 10 mg tablet, 28

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
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<th>MRVSN</th>
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</table>
**NERVOUS SYSTEM**

### ESCITALOPRAM

**Restricted benefit**
- Major depressive disorders

**Restricted benefit**
- Moderate to severe generalised anxiety disorder (GAD)

**Clinical criteria:**
- The condition must be defined by Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) criteria, **AND**
- Patient must not have responded to non-pharmacological therapy, **AND**
- Patient must be one for whom a GP Mental Health Care Plan, as described under items 2715 or 2717 of the Medicare Benefits Schedule, has been prepared.

**Restricted benefit**
- Moderate to severe generalised anxiety disorder (GAD)

**Clinical criteria:**
- The condition must be defined by Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) criteria, **AND**
- Patient must not have responded to non-pharmacological therapy, **AND**
- Patient must have been assessed by a psychiatrist.

**Restricted benefit**
- Moderate to severe social anxiety disorder (social phobia, SAD)

**Clinical criteria:**
- The condition must be defined by Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) criteria, **AND**
- Patient must not have responded to non-pharmacological therapy, **AND**
- Patient must have been assessed by a psychiatrist.

---

**escitalopram 20 mg/mL oral liquid, 15 mL**

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### FLUOXETINE

**Restricted benefit**
- Major depressive disorders

**Restricted benefit**
- Obsessive-compulsive disorder

**fluoxetine 20 mg capsule, 28**

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<tr>
<th>Max.Qty Packs</th>
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**fluoxetine 20 mg tablet: dispersible, 28**

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### FLUOXAMINE

**Restricted benefit**
- Major depressive disorders

**Restricted benefit**
- Obsessive-compulsive disorder

**fluvoxamine maleate 100 mg tablet, 30**

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NERVOUS SYSTEM

Schedule of Pharmaceutical Benefits

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**fluvoxamine maleate 50 mg tablet, 30**

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- **PAROXETINE**
  - Restricted benefit
  - Major depressive disorders
  - Restricted benefit
  - Obsessive-compulsive disorder
  - Restricted benefit
  - Panic disorder

**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.

**paroxetine 20 mg tablet, 30**

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<td>*Paroxetine Sandoz [SZ]</td>
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**paroxetine 20 mg tablet, 30**

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<td>*Eleva 100 [AF]</td>
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**sertraline 100 mg tablet, 30**

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**sertraline 50 mg tablet, 30**

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- **SERTRALINE**
  - Restricted benefit
  - Major depressive disorders

- **SERTRALINE**
  - Restricted benefit
  - Obsessive-compulsive disorder
**NERVOUS SYSTEM**

**Restricted benefit**
Panic disorder where other treatments have failed or are inappropriate

### sertraline 100 mg tablet, 30

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<td>* Sertraline AN [EA]</td>
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**Sertraline 50 mg tablet, 30**

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**Monoamine oxidase inhibitors, non-selective**

#### PHENELZINE

**Caution**
This drug is an irreversible monoamine oxidase inhibitor.

**Restricted benefit**
Depression where all other anti-depressant therapy has failed or is inappropriate

### phenelzine 15 mg tablet, 100

| Max Qty | Packs | No. of Rpts | Premium $ | DPMO $ | MRVSN $ | Brand Name and Manufacturer |
|---------|-------|-------------|-----------|---------|----------|----------------------------|---------------------------|
| 1       | 1     | ..          | 100.44    | 37.70   | ..       | Nardil [LM]                 |                           |

#### TRANYLCYPROMINE

**Caution**
This drug is an irreversible monoamine oxidase inhibitor.

### tranylcypromine 10 mg tablet, 50

| Max Qty | Packs | No. of Rpts | Premium $ | DPMO $ | MRVSN $ | Brand Name and Manufacturer |
|---------|-------|-------------|-----------|---------|----------|----------------------------|---------------------------|
| 1       | 2     | ..          | 58.66     | 37.70   | ..       | Parnate [GH]                |                           |

**Monoamine oxidase A inhibitors**

#### MOCLOBEMIDE

**Restricted benefit**
Major depressive 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.

### moclobemide 150 mg tablet, 60

| Max Qty | Packs | No. of Rpts | Premium $ | DPMO $ | MRVSN $ | Brand Name and Manufacturer |
|---------|-------|-------------|-----------|---------|----------|----------------------------|---------------------------|
| 1       | 5     | ..          | 13.14     | 14.29   | ..       | * Amira 150 [AF]             | * Chem mart Moclobemide [CH] |
|         |       |             |           |         |          | * Clobemix [GN]             | * GenRx Moclobemide [GX]   |
|         |       |             |           |         |          | * Moclobemide AN [EA]       | * Moclobemide Sandoz [SZ]  |
|         |       |             |           |         |          | * Mohexal [HX]              | * Terry White Chemists     |
|         |       |             |           |         |          | Moclobemide [TW]            |                           |

### moclobemide 300 mg tablet, 60

| Max Qty | Packs | No. of Rpts | Premium $ | DPMO $ | MRVSN $ | Brand Name and Manufacturer |
|---------|-------|-------------|-----------|---------|----------|----------------------------|---------------------------|
| 1       | 5     | ..          | 19.04     | 20.19   | ..       | * Amira 300 [AF]             | * Chem mart Moclobemide [CH] |
|         |       |             |           |         |          | * Clobemix [GN]             | * GenRx Moclobemide [GX]   |
|         |       |             |           |         |          | * Moclobemide AN [EA]       | * Moclobemide Sandoz [SZ]  |
|         |       |             |           |         |          | * Terry White Chemists     |                           |
|         |       |             |           |         |          | Moclobemide [TW]            |                           |

**Other antidepressants**

#### DESVENLAFAXINE

**Restricted benefit**
Major depressive disorders
**NERVOUS SYSTEM**

**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.

Pharmaceutical benefits that have the forms desvenlafaxine tablet (modified release) 50 mg, desvenlafaxine tablet (modified release) 50 mg (as benzoate) and desvenlafaxine tablet (extended release) 50 mg (as succinate) are equivalent for the purposes of substitution.

Pharmaceutical benefits that have the forms desvenlafaxine tablet (modified release) 100 mg, desvenlafaxine tablet (modified release) 100 mg (as benzoate) and desvenlafaxine tablet (extended release) 100 mg (as succinate) are equivalent for the purposes of substitution.

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**DULOXETINE**

**Restricted benefit**
Major depressive 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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Schedule of Pharmaceutical Benefits 493
NERVOUS SYSTEM

- **LITHIUM CARBONATE**

  **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.

  **lithium carbonate 250 mg tablet, 200**

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  **lithium carbonate 450 mg tablet: modified release, 100 tablets**

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- **MIANSERIN**

  **Caution**
  Neutropenia and agranulocytosis are more frequent in the elderly, especially in the early months of therapy.

  **Restricted benefit**
  Severe depression

  **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.

  **mianserin hydrochloride 10 mg tablet, 50**

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  **mianserin hydrochloride 20 mg tablet, 50**

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- **MIRTAZAPINE**

  **Restricted benefit**
  Major depressive 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.

  **MIRTAZAPINE Tablet 15 mg (orally disintegrating), 30**

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  **MIRTAZAPINE Tablet 30 mg (orally disintegrating), 30**

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  **MIRTAZAPINE Tablet 45 mg (orally disintegrating), 30**

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</table>
### NERVOUS SYSTEM

#### Schedule of Pharmaceutical Benefits

<table>
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<tr>
<th>NERVOUS SYSTEM</th>
<th>REBOXETINE</th>
<th>VENLAFAXINE</th>
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</table>

#### REBOXETINE

**Restricted benefit**

Major depressive 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.

#### VENLAFAXINE

**Restricted benefit**

Major depressive disorders

**Note**

Continuing Therapy Only:

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

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### mirtazapine 15 mg tablet, 30

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<td>* Axit 15 [AF]</td>
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### mirtazapine 30 mg tablet, 30

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### mirtazapine 45 mg tablet, 30

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### reboxetine 4 mg tablet, 60

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### venlafaxine 150 mg capsule: modified release, 28 capsules

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### venlafaxine 37.5 mg capsule: modified release, 28 capsules

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Schedule of Pharmaceutical Benefits 495
NERVOUS SYSTEM

venlafaxine 75 mg capsule: modified release, 28 capsules

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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 contra indication 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.

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

atomoxetine 10 mg capsule, 28

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atomoxetine 100 mg capsule, 28

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atomoxetine 18 mg capsule, 28

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atomoxetine 25 mg capsule, 28

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atomoxetine 40 mg capsule, 28

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atomoxetine 60 mg capsule, 28
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atomoxetine 80 mg capsule, 28
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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.

**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.

dexamphetamine sulfate 5 mg tablet, 100
1165H

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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 12 hours

**Note**  
Care must be taken to comply with the provisions of State/Territory law when prescribing methylphenidate hydrochloride.

**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.

methylphenidate hydrochloride 18 mg tablet: modified release, 30 tablets
2387P

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methylphenidate hydrochloride 27 mg tablet: modified release, 30 tablets
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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.

**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.
methylphenidate hydrochloride 10 mg capsule: modified release, 30 capsules

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### METHYLPHENIDATE

**Authority required**

Use in attention deficit hyperactivity disorder, in accordance with State/Territory law.

**Note**

Care must be taken to comply with the provisions of State/Territory law when prescribing methylphenidate hydrochloride.

**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.

methylphenidate hydrochloride 10 mg tablet, 100

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### MODAFINIL

**Authority required**

Initial treatment, by a qualified sleep medicine practitioner or neurologist, of patients with narcolepsy where:

(i) therapy with dexamphetamine sulfate poses an unacceptable medical risk; or
(ii) intolerance to dexamphetamine sulfate of a severity necessitating treatment withdrawal develops.

The presence of any 1 of the following indicates treatment with dexamphetamine sulfate poses an unacceptable medical risk:

(a) a psychiatric disorder;
(b) a cardiovascular disorder;
(c) a history of substance abuse;
(d) glaucoma;
(e) any other absolute contraindication to dexamphetamine sulfate as specified in the TGA-approved Product Information.

Patients must meet the following definition of narcolepsy:

Excessive daytime sleepiness, recurrent naps or lapses into sleep occurring almost daily for at least 3 months and:

(i) a definite history of cataplexy; or
(ii) 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.

Modafinil is not PBS-subsidised when used in combination with PBS-subsidised dexamphetamine sulfate.

### modafinil 100 mg tablet, 60

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### ANTI-DEMENTIA DRUGS

#### Anticholinesterases

- **DONEPEZIL**
  - **Authority required (STREAMLINED)**
  - **4219**
    - Mild to moderately severe Alzheimer disease
    - Treatment Phase: Continuing

  **Clinical criteria:**
  - Patient must have received six months of sole PBS-subsidised initial therapy with this drug, **AND**
  - Patient must demonstrate a clinically meaningful response to the initial treatment, **AND**
  - The treatment must be the sole PBS-subsidised therapy for this condition.

  Prior to continuing treatment, a comprehensive assessment must be undertaken and documented, involving the patient, the patient's family or carer and the treating physician to establish agreement that treatment is continuing to produce worthwhile benefit.

  Treatment should cease if there is no agreement of benefit as there is always the possibility of harm from unnecessary use.

  Re-assessments for a clinically meaningful response are to be undertaken and documented every six months.

  Clinically meaningful response to treatment is demonstrated in the following areas:
  - Patient's quality of life including but not limited to level of independence and happiness;
  - Patient's cognitive function including but not limited to memory, recognition and interest in environment;
  - Patient's behavioural symptoms, including but not limited to hallucination, delusions, anxiety, marked agitation or associated aggressive behaviour.

**Note**

Continuing Therapy Only:

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

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### donepezil hydrochloride 5 mg tablet, 28

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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 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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**donepezil hydrochloride 10 mg tablet, 28**

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**NERVOUS SYSTEM**
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.

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**galantamine 16 mg capsule: modified release, 28 capsules**

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<td>* Gamine XR [QA]</td>
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**galantamine 8 mg capsule: modified release, 28 capsules**

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<td>* Gamine XR [QA]</td>
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**GALANTAMINE**

**Authority required**
Mild to moderately severe Alzheimer disease
Treatment Phase: Initial

**Clinical criteria:**
Patient must have a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 10 or more, **AND**
The condition must be confirmed by, or in consultation with, a specialist/consultant physician (including a psychiatrist), **AND**
The treatment must be the sole PBS-subsidised therapy for this condition.
The authority application must include the result of the baseline MMSE or SMMSE. If this score is 25 - 30 points, the result of a baseline Alzheimer Disease Assessment Scale, cognitive sub-scale (ADAS-Cog) may also be specified.
The application must be made in writing, but initial supply may be sought by telephone.
For telephone applications, up to a maximum of 2 months' initial therapy will be authorised. This telephone application must be followed by a written authority application for no more than 1 month's therapy and sufficient repeats to complete a maximum of up to 6 months' initial treatment.
For written applications where no prior telephone approval has been issued, up to a maximum of 1 month's therapy plus 5 repeats will be authorised.

**Authority required**
Mild to moderately severe Alzheimer disease
Treatment Phase: Initial

**Clinical criteria:**
Patient must have a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 9 or less, **AND**
The condition must be confirmed by, or in consultation with, a specialist/consultant physician (including a psychiatrist), **AND**
The treatment must be the sole PBS-subsidised therapy for this condition. A patient who is unable to register a score of 10 or more for reasons other than their Alzheimer disease, as specified below. Such patients will need to be assessed using the Clinicians Interview Based Impression of Severity (CIBIS) scale. The authority application must include the result of the baseline (S)MMSE and specify to which group(s) (see below) the patient belongs.

Patients who qualify under this criterion are from 1 or more of the following groups:
1. Unable to communicate adequately because of lack of competence in English, in people of non-English speaking background;
2. Limited education, as defined by less than 6 years of education, or who are illiterate or innumerate;
3. Aboriginal or Torres Strait Islanders who, by virtue of cultural factors, are unable to complete an (S)MMSE test;
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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**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:**
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.
NERVOUS SYSTEM

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.

rivastigmine 1.5 mg capsule, 56
8497F
Max Qty Packs No. of Rpts Premium $ DPMO $ MRVSN $ Brand Name and Manufacturer
1 5 . . 96.18 37.70 Exelon [NV]

rivastigmine 2 mg/mL oral liquid, 120 mL
8563Q
Max Qty Packs No. of Rpts Premium $ DPMO $ MRVSN $ Brand Name and Manufacturer
‡1 5 . . 96.18 37.70 Exelon [NV]

rivastigmine 3 mg capsule, 56
8498G
Max Qty Packs No. of Rpts Premium $ DPMO $ MRVSN $ Brand Name and Manufacturer
1 5 . . 96.18 37.70 Exelon [NV]

rivastigmine 4.5 mg capsule, 56
8499H
Max Qty Packs No. of Rpts Premium $ DPMO $ MRVSN $ Brand Name and Manufacturer
1 5 . . 96.18 37.70 Exelon [NV]

rivastigmine 4.6 mg/24 hours patch, 30
9161E
Max Qty Packs No. of Rpts Premium $ DPMO $ MRVSN $ Brand Name and Manufacturer
1 5 . . 102.56 37.70 Exelon Patch 5 [NV]

rivastigmine 6 mg capsule, 56
8500J
Max Qty Packs No. of Rpts Premium $ DPMO $ MRVSN $ Brand Name and Manufacturer
1 5 . . 96.18 37.70 Exelon [NV]

rivastigmine 9.5 mg/24 hours patch, 30
9162F
Max Qty Packs No. of Rpts Premium $ DPMO $ MRVSN $ Brand Name and Manufacturer
1 5 . . 102.56 37.70 Exelon Patch 10 [NV]

Other anti-dementia drugs

MEMANTINE

Authority required (STREAMLINED)
4214
Moderately severe Alzheimer disease
Treatment Phase: Continuing

Clinical criteria:
Patient must have received six months of sole PBS-subsidised initial therapy with this drug, AND
Patient must demonstrate a clinically meaningful response to the initial treatment, AND
The treatment must be the sole PBS-subsidised therapy for this condition.
Prior to continuing treatment, a comprehensive assessment must be undertaken and documented, involving the patient, the patient's family or carer and the treating physician to establish agreement that treatment is continuing to produce worthwhile benefit.
Treatment should cease if there is no agreement of benefit as there is always the possibility of harm from unnecessary use.
Re-assessments for a clinically meaningful response are to be undertaken and documented every six months.
Clinically meaningful response to treatment is demonstrated in the following areas:
Patient's quality of life including but not limited to level of independence and happiness;
Patient's cognitive function including but not limited to memory, recognition and interest in environment;
Patient's behavioural symptoms, including but not limited to hallucination, delusions, anxiety, marked agitation or associated aggressive behaviour.

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

Authority required

Moderately severe Alzheimer disease

Treatment Phase: Initial

Clinical criteria:

Patient must have a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 10 to 14, AND The condition must be confirmed by, or in consultation with, a specialist/consultant physician (including a psychiatrist), AND The treatment must be the sole PBS-subsidised therapy for this condition.

The application must include the result of the baseline MMSE or SMMSE of 10 to 14.

For telephone applications, up to a maximum of 2 months' initial therapy will be authorised. This telephone application must be followed by a written authority application for no more than 1 month's therapy and sufficient repeats to complete a maximum of up to 6 months' initial treatment.

For written applications where no prior telephone approval has been issued, up to a maximum of 1 month's therapy plus 5 repeats will be authorised.

Authority required

Moderately severe Alzheimer disease

Treatment Phase: Initial

Clinical criteria:

Patient must have a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 9 or less, AND The condition must be confirmed by, or in consultation with, a specialist/consultant physician (including a psychiatrist), AND The treatment must be the sole PBS-subsidised therapy for this condition.

A patient who is unable to register a score of 10 to 14 for reasons other than their Alzheimer disease, as specified below. Such patients will need to be assessed using the Clinicians Interview Based Impression of Severity (CIBIS) scale. The authority application must include the result of the baseline (S)MMSE and specify to which group(s) (see below) the patient belongs.

Patients who qualify under this criterion are from 1 or more of the following groups:

1. Unable to communicate adequately because of lack of competence in English, in people of non-English speaking background;
2. Limited education, as defined by less than 6 years of education, or who are illiterate or innumerate;
3. Aboriginal or Torres Strait Islanders who, by virtue of cultural factors, are unable to complete an (S)MMSE test;
4. Intellectual (developmental or acquired) disability, eg Down's syndrome;
5. Significant sensory impairment despite best correction, which precludes completion of an (S)MMSE test;
6. Prominent dysphasia, out of proportion to other cognitive and functional impairment.

The application must be made in writing, but initial supply may be sought by telephone.

For telephone applications, up to a maximum of 2 months' initial therapy will be authorised. This telephone application must be followed by a written authority application for no more than 1 month's therapy and sufficient repeats to complete a maximum of up to 6 months' initial 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 hydrochloride 20 mg tablet, 28

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- **OTHER NERVOUS SYSTEM DRUGS**

## PARASYMPATHOMIMETICS

### Anticholinesterases

#### PYRIDOSTIGMINE

**PYRIDOSTIGMINE BROMIDE Tablet 10 mg, 50**

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**pyridostigmine bromide 180 mg tablet: modified release, 50 tablets**

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**pyridostigmine bromide 60 mg tablet, 150**

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### Choline esters

#### BETHANECHOL

**bethanechol chloride 10 mg tablet, 100**

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- **DRUGS USED IN ADDICTIVE DISORDERS**

**Drugs used in nicotine dependence**

#### 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.

**bupropion hydrochloride 150 mg tablet: modified release, 90 tablets**

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<tr>
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<td>177.46</td>
<td>37.70</td>
<td>* Zyban [AS]</td>
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#### BUPROPION

**Authority required**

Commencement of short-term, sole PBS-subsidised, therapy as an aid to achieving abstinence in a patient who has indicated they are ready to cease smoking and who has entered a comprehensive support and counselling program. Details of the program must be specified in the authority application

**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.
bupropion hydrochloride 150 mg tablet: modified release, 30 tablets

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### NICOTINE

**Authority required (STREAMLINED)**

**4348**

Nicotine dependence

**Clinical criteria:**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have indicated they are ready to cease smoking, **AND**
- Patient must have entered a comprehensive support and counselling program, **AND**
- Patient must not receive more than 12 weeks of PBS-subsidised nicotine replacement therapy per 12-month period.
- Details of the support and counselling program must be documented in the patient's medical records at the time treatment is initiated.

**Authority required (STREAMLINED)**

**4307**

Nicotine dependence

**Clinical criteria:**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have indicated they are ready to cease smoking, **AND**
- Patient must be entering a comprehensive support and counselling program during the consultation at which this prescription is written, **AND**
- Patient must not receive more than 12 weeks of PBS-subsidised nicotine replacement therapy per 12-month period.
- Details of the support and counselling program must be documented in the patient's medical records at the time treatment is initiated.

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

**nicotine 14 mg/24 hours patch, 28**

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**nicotine 21 mg/24 hours patch, 28**

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**nicotine 7 mg/24 hours patch, 28**

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

**nicotine 21 mg/24 hours patch, 28**

<table>
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<th>Code</th>
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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.

Authority required [STREAMLINED]
4348
Nicotine dependence
Clinical criteria:
The treatment must be the sole PBS-subsidised therapy for this condition, AND
Patient must have indicated they are ready to cease smoking, AND
Patient must have entered a comprehensive support and counselling program, AND
Patient must not receive more than 12 weeks of PBS-subsidised nicotine replacement therapy per 12-month period.
Details of the support and counselling program must be documented in the patient's medical records at the time treatment is initiated.

Authority required (STREAMLINED)
4307
Nicotine dependence
Clinical criteria:
The treatment must be the sole PBS-subsidised therapy for this condition, AND
Patient must have indicated they are ready to cease smoking, AND
Patient must be entering a comprehensive support and counselling program during the consultation at which this prescription is written, AND
Patient must not receive more than 12 weeks of PBS-subsidised nicotine replacement therapy per 12-month period.
Details of the support and counselling program must be documented in the patient's medical records at the time treatment is initiated.

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

nicotine 21 mg/24 hours patch, 28

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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nicotine 25 mg/16 hours patch, 28

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</table>

Varenicline

Authority required
Nicotine dependence
Treatment Phase: Completion of a short-term (24 weeks) course of treatment
Clinical criteria:
The treatment must be as an aid to achieving abstinence from smoking, AND
The treatment must be the sole PBS-subsidised therapy for this condition, AND
Patient must have previously been issued with an authority prescription for this drug during this current course of treatment, AND
Patient must have ceased smoking in the process of completing an initial 12-weeks or ceased smoking following an initial 12-weeks of PBS-subsidised treatment with this drug in the current course of treatment.

Treatment criteria:
Patient must be undergoing concurrent counselling for smoking cessation through a comprehensive support and counselling program.

Note
A course of treatment with this drug is 12 weeks or up to 24 weeks, if initial treatment of 12 weeks has been successful.
A patient may only qualify for PBS-subsidised treatment under this treatment phase restriction once during a short-term course of treatment.
No increase in the maximum quantity or number of units may be authorised.
No increase in the maximum number of repeats may be authorised.

Varenicline 1 mg tablet, 56

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
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<td>120.76</td>
<td>37.70 Champix [PF]</td>
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</table>
NERVOUS SYSTEM

**VARENICLINE**

*Authority required*

Nicotine dependence

**Treatment Phase: Continuation of a short-term (12 weeks or 24 weeks) course of treatment**

**Clinical criteria:**

- The treatment must be as an aid to achieving abstinence from smoking, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have previously been issued with an authority prescription for this drug during this current course of treatment.

**Treatment criteria:**

- Patient must be undergoing concurrent counselling for smoking cessation through a comprehensive support and counselling program.

**Note**

- A course of treatment with this drug is 12 weeks or up to 24 weeks, if initial treatment of 12 weeks has been successful.
- A patient may only qualify for PBS-subsidised treatment under this treatment phase restriction once during a short-term course of treatment.
- No increase in the maximum quantity or number of units may be authorised.
- No increase in the maximum number of repeats may be authorised.

<table>
<thead>
<tr>
<th>Varenicline 1 mg tablet, 56</th>
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<tr>
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<td></td>
<td>232.04</td>
<td>37.70</td>
<td>Champix [PF]</td>
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</table>

**VARENICLINE**

*Authority required*

Nicotine dependence

**Treatment Phase: Commencement of a short-term (12 weeks or 24 weeks) course of treatment**

**Clinical criteria:**

- The treatment must be as an aid to achieving abstinence from smoking, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have indicated they are ready to cease smoking.

**Treatment criteria:**

- Patient must be undergoing concurrent counselling for smoking cessation through a comprehensive support and counselling program or is about to enter such a program at the time the Authority application is requested.

- Details of the support and counselling program must be documented in the patient's medical records at the time treatment is initiated.

- Clinical review is recommended within 2 to 3 weeks of the initial prescription being requested.

**Note**

- A course of treatment with this drug is 12 weeks or up to 24 weeks, if initial treatment of 12 weeks has been successful.
- The period between commencing varenicline and bupropion or a new course of varenicline must be at least 6 months.
- A patient may only qualify for PBS-subsidised treatment under this treatment phase restriction once during a short-term course of treatment.
- No increase in the maximum quantity or number of units may be authorised.
- No increase in the maximum number of repeats may be authorised.

<table>
<thead>
<tr>
<th>Varenicline 500 microgram tablet [11 tablets] (&amp;) varenicline 1 mg tablet [42 tablets], 53</th>
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</table>

**ACAMPROSATE**

*Authority required (STREAMLINED)*

2665

For use within a comprehensive treatment program for alcohol dependence with the goal of maintaining abstinence

**Note**

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

<table>
<thead>
<tr>
<th>Acamprosate calcium 333 mg tablet: enteric, 180 tablets</th>
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</thead>
<tbody>
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<td>8357W</td>
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<table>
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<td>166.92</td>
<td>37.70</td>
<td>Campral [AF]</td>
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</tbody>
</table>

**NALTREXONE**

**Caution**

Naltrexone hydrochloride is contraindicated in patients receiving opioid drugs.

*Authority required*
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 hydrochloride 50 mg tablet, 30

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<td><strong>NP</strong></td>
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</table>

**Other nervous system drugs**

- **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.

- **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.
    - No increase in the maximum number of repeats may be authorised.
    - Special Pricing Arrangements apply.
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**

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

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

Special Pricing Arrangements apply.

dimethyl fumarate 240 mg capsule: modified release, 56 capsules

<table>
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<td>1880.00</td>
<td>37.70</td>
<td>Tecfidera [BD]</td>
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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
2. have not undergone tracheostomy, and
3. have not experienced respiratory failure; **OR**
4. are not ambulatory, and
5. have not undergone tracheostomy, and
6. have not experienced respiratory failure, and
7. 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
2. have not undergone tracheostomy, and
3. have not experienced respiratory failure; **OR**
4. are not ambulatory, and
5. have not undergone tracheostomy, and
6. have not experienced respiratory failure, and
7. 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.

riluzole 50 mg tablet, 56

<table>
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<td>37.70</td>
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<td></td>
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<td></td>
<td>* Pharmaco Riluzole [CR]</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>* Rilutek [SW]</td>
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**TETRABENAZINE**

**Authority required (STREAMLINED)**

1161

Hyperkinetic extrapyramidal disorders

**Note**

Continuing Therapy Only:

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

tetrabenazine 25 mg tablet, 112

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<td></td>
<td></td>
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<td>(Australia) Pty Ltd [IA]</td>
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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.

atovaquone 750 mg/5 mL oral liquid, 210 mL

<table>
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<tr>
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<tr>
<td>8300W</td>
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<td>1034.91</td>
<td>37.70</td>
<td>Wellvone [AS]</td>
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**PYRIMETHAMINE**

pyrimethamine 25 mg tablet, 50

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<td>16.72</td>
<td>17.87</td>
<td>Daraprim [AS]</td>
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</table>

**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.

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.

atovaquone 250 mg + proguanil hydrochloride 100 mg tablet, 12

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</table>

**Methanolquinolines**

**QUININE**

*Caution*

Severe thrombocytopenia has been reported with this drug.

*Authority required (STREAMLINED)*

2142

Malaria

quinine sulfate 300 mg tablet, 50

<table>
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<tr>
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<tbody>
<tr>
<td>1975Y</td>
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<td>14.48</td>
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<td>Quinate [AS]</td>
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**Artesimin and derivatives, combinations**

**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 lumefantrine

**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*

**Note**

Artemether with lumefantrine is not PBS-subsidised for prophylaxis of malaria.

<table>
<thead>
<tr>
<th>Artemether 20 mg + lumefantrine 120 mg tablet: dispersible, 18</th>
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<tbody>
<tr>
<td>5296R Max.Qty Packs No. of Rpts Premium $ DPMO $ MRVSN $ Brand Name and Manufacturer</td>
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<td>1 .. .. 97.24 37.70 Riamet 20mg/120mg Dispersible [NV]</td>
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### ANTHELMINTICS

#### ANTITREMATODALS

**Quinoline derivatives and related substances**

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<tr>
<td>1 .. .. 41.19 37.70 Biltricide [BN]</td>
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### ANTINEMATODAL AGENTS

**Benzimidazole derivatives**

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<table>
<thead>
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<th>Albendazole 200 mg tablet: chewable, 6</th>
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<table>
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<tr>
<td>1 .. .. 33.44 34.59 Zentel [AS]</td>
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**Tetrahydropyrimidine derivatives**
### PYRANTEL

pyrantel 125 mg tablet, 6

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pyrantel 250 mg tablet, 6

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### AVERMECTINES

#### IVERMECTIN

**Authority required (STREAMLINED)**

**Onchocerciasis**

ivermectin 3 mg tablet, 4

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<td>Stromectol [MK]</td>
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</table>

**Strongyloidiasis**

**Authority required (STREAMLINED)**

**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.

**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.

#### 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.

**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.

### ECTOPARASITICIDES, INCL. SCABICIDES, INSECTICIDES AND REPELLENTS

#### ECTOPARASITICIDES, INCL. SCABICIDES

**Pyrethrines, incl. synthetic compounds**

#### PERMETHRIN

permethrin 5% cream, 30 g

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
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<td>3054R</td>
<td></td>
<td></td>
<td>17.11</td>
<td>18.26</td>
<td>Lyclear [JT]</td>
</tr>
</tbody>
</table>
RESPIRATORY SYSTEM

NASAL PREPARATIONS

DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE

Other nasal preparations

MUPIROCIN

Authority required (STREAMLINED)

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.

Mupirocin 2% (20 mg/g) ointment, 3 g

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
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<tbody>
<tr>
<td>9440W</td>
<td></td>
<td>20.97</td>
<td>22.12</td>
<td></td>
<td>Bactroban [GK]</td>
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DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES

ADRENERGICS, INHALANTS

Selective beta-2-adrenoreceptor agonists

EFORMETEROL

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

eformoterol fumarate dihydrate 12 microgram inhalation: powder for, 60 capsules

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
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<th>Premium $</th>
<th>DPMQ $</th>
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<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>8136F</td>
<td>1</td>
<td>37.67</td>
<td>37.70</td>
<td></td>
<td>Foradile [NV]</td>
</tr>
</tbody>
</table>

eformoterol fumarate dihydrate 12 microgram/actuation inhalation: powder for, 60 actuations

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<thead>
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<tbody>
<tr>
<td>8240Q</td>
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</table>

eformoterol fumarate dihydrate 6 microgram/actuation inhalation: powder for, 60 actuations

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<tr>
<td>8239P</td>
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<td>26.72</td>
<td>27.87</td>
<td></td>
<td>Oxis Turbuhaler [AP]</td>
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</table>

INDACATEROL

Restricted benefit

Chronic obstructive pulmonary disease

Note

Indacaterol is not PBS-subsidised for the treatment of asthma.

Indacaterol 150 microgram inhalation: powder for, 30 capsules

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>5134F</td>
<td>1</td>
<td>62.73</td>
<td>37.70</td>
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<td>Onbrez [NV]</td>
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</table>

Indacaterol 300 microgram inhalation: powder for, 30 capsules

<table>
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<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>5137J</td>
<td>1</td>
<td>62.73</td>
<td>37.70</td>
<td></td>
<td>Onbrez [NV]</td>
</tr>
</tbody>
</table>

SALBUTAMOL

Salbutamol 100 microgram/actuation inhalation: pressurised, 200

<table>
<thead>
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<th>DPMQ $</th>
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</thead>
<tbody>
<tr>
<td>8288F</td>
<td>2</td>
<td>*14.14</td>
<td>15.29</td>
<td></td>
<td>APO-Salbutamol Inhaler [TX]</td>
</tr>
<tr>
<td></td>
<td></td>
<td>*2.34</td>
<td>*16.48</td>
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<td>Asmol CFC-free [AL]</td>
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Salbutamol 200 microgram inhalation: powder for, 128 capsules

<table>
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</thead>
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<tr>
<td>10143W</td>
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<td>*19.12</td>
<td>20.27</td>
<td></td>
<td>Ventolin Rotacaps [GK]</td>
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• **SALBUTAMOL**
  
  **Restricted benefit**
  Patients unable to achieve co-ordinated use of other metered dose inhalers containing this drug

  **salbutamol Oral pressurised inhalation in breath actuated device 100 micrograms (base) per dose (200 doses), CFC-free formulation, 1**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium ($)</th>
<th>DPMQ ($)</th>
<th>MRVSN ($)</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>8354Q</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Airomir Autohaler [IA]</td>
</tr>
</tbody>
</table>

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

<table>
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<th>No. of Rpts</th>
<th>Premium ($)</th>
<th>DPMQ ($)</th>
<th>MRVSN ($)</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>2000G</td>
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</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium ($)</th>
<th>DPMQ ($)</th>
<th>MRVSN ($)</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>2001H</td>
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<td></td>
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</tbody>
</table>

• **SALMETEROL**

  **Restricted benefit**
  Patients with frequent episodes of asthma who are currently receiving treatment with oral corticosteroids

  **TERBUTALINE**

  terbutaline sulfate 500 microgram/actuation inhalation: powder for, 150 actuations

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium ($)</th>
<th>DPMQ ($)</th>
<th>MRVSN ($)</th>
<th>Brand Name and Manufacturer</th>
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<tr>
<td>1205L</td>
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</table>

• **BUDESONIDE + EFOMOTEROL**

  **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 and require single maintenance and reliever therapy.

  **Population criteria:**
  Patient must be aged 12 years or over.
BUDESONIDE + EFORMOTEROL

Restricted benefit

Asthma

Clinical criteria:
Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids; 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.

BUDESONIDE + EFORMOTEROL

Restricted benefit

Chronic obstructive pulmonary disease (COPD)

Clinical criteria:
Patient must have a forced expiratory volume in 1 second (FEV1) less than 50% of predicted normal prior to therapy, AND
Patient must have a history of repeated exacerbations with significant symptoms despite regular beta-2 agonist bronchodilator therapy, AND
The treatment must be for symptomatic treatment.

Note
Patient must not be on a concomitant single agent long-acting beta-2 agonist. This product is not indicated for the initiation of bronchodilator therapy in COPD.
Clinical criteria:
Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids.

Population criteria:
Patient must be aged 12 years or over.

Note
Unlike Symbicort Turbuhaler 200/6, Symbicort Rapihaler 200/6 is not recommended nor PBS-subsidised for use as ‘maintenance and reliever’ therapy as the approved Product Information does not specify such use.

Restricted benefit
Chronic obstructive pulmonary disease (COPD)

Clinical criteria:
Patient must have a forced expiratory volume in 1 second (FEV1) less than 50% of predicted normal prior to therapy, AND Patient must have a history of repeated exacerbations with significant symptoms despite regular beta-2 agonist bronchodilator therapy, AND The treatment must be for symptomatic treatment.

Note
Patient must not be on a concomitant single agent long-acting beta-2 agonist.

This product is not indicated for the initiation of bronchodilator therapy in COPD.

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
</tr>
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<tbody>
<tr>
<td>2827T</td>
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</table>

### FLUTICASONE + EFORMOTEROL

<table>
<thead>
<tr>
<th>FLUTICASONE + EFORMOTEROL</th>
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</thead>
</table>

Restricted benefit
Asthma

Clinical criteria:
Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids.

Population criteria:
Patient must be aged 12 years or over.

Note
Flutiform is not recommended nor PBS-subsidised for use as ‘maintenance and reliever’ therapy.

Flutiform is not indicated or PBS-subsidised for bronchodilator therapy in COPD.

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>flutiform 50/5 [MF]</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>flutiform 125/5 [MF]</td>
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</table>

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>flutiform 250/10 [MF]</td>
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</table>

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>flutiform 250/10 [MF]</td>
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</table>

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>flutiform 50/5 [MF]</td>
</tr>
</tbody>
</table>
**FLUTICASONE + SALMETEROL**

**Restricted benefit**

**Asthma**

**Clinical criteria:**
Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids.

**Population criteria:**
Patient must be aged 4 years or older.

**Restrict benefit**

**Chronic obstructive pulmonary disease (COPD)**

**Clinical criteria:**
Patient must have a forced expiratory volume in 1 second (FEV1) less than 50% of predicted normal prior to therapy, **AND** Patient must have a history of repeated exacerbations with significant symptoms despite regular beta-2 agonist bronchodilator therapy, **AND** The treatment must be for symptomatic treatment.

**Note**
Patient must not be on a concomitant single agent long-acting beta-2 agonist.

This product is not indicated for the initiation of bronchodilator therapy in COPD.

---

**FLUTICASONE + VILANTEROL**

**Restricted benefit**

**Asthma**

**Clinical criteria:**
Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids.

**Population criteria:**
Patient must be aged 12 years or over.

**Note**
This drug is not recommended nor PBS-subsidised for use as ‘maintenance and reliever’ therapy. This drug is not PBS-subsidised for the treatment of chronic obstructive pulmonary disease (COPD).
**FLUTICASONE + VILANTEROL**

**Restricted benefit**

**Asthma**

**Clinical criteria:**
Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids.

**Population criteria:**
Patient must be aged 12 years or over.

**Note**
This drug is not recommended nor PBS-subsidised for use as ‘maintenance and reliever’ therapy.

**Restricted benefit**

**Chronic obstructive pulmonary disease (COPD)**

**Clinical criteria:**
Patient must have a forced expiratory volume in 1 second (FEV1) less than 50% of predicted normal prior to therapy, **AND**
Patient must have a history of repeated exacerbations with significant symptoms despite regular beta-2 agonist bronchodilator therapy, **AND**
The treatment must be for symptomatic treatment.

**Note**
Patient must not be on a concomitant single agent long-acting beta-2 agonist.
This product is not indicated for the initiation of bronchodilator therapy in COPD.

---

**INDACATEROL + GLYCOPYRRONIUM**

**Authority required (STREAMLINED)**

**4655**

**Chronic obstructive pulmonary disease (COPD)**

**Clinical criteria:**
Patient must have been stabilised on a combination of a long acting muscarinic antagonist and long acting beta-2 agonist.

**Note**
The treatment must not be used in combination with an ICS/LABA, or LAMA or LABA monotherapy.
A LAMA includes tiotropium, glycopyrronium, aclidinium or umeclidinium.
A LABA includes indacaterol, salmeterol, eformoterol or vilanterol.
This product is not PBS-subsidised for the treatment of asthma.
This product is not indicated for the initiation of bronchodilator therapy in COPD.

---

**UMECLIDINIUM + VILANTEROL**

**Authority required (STREAMLINED)**

**4655**

**Chronic obstructive pulmonary disease (COPD)**

**Clinical criteria:**
Patient must have been stabilised on a combination of a long acting muscarinic antagonist and long acting beta-2 agonist.

**Note**
The treatment must not be used in combination with an ICS/LABA, or LAMA or LABA monotherapy.
A LAMA includes tiotropium, glycopyrronium, aclidinium or umeclidinium.
A LABA includes indacaterol, salmeterol, eformoterol or vilanterol.
This product is not PBS-subsidised for the treatment of asthma.
This product is not indicated for the initiation of bronchodilator therapy in COPD.
umeclidinium 62.5 microgram/actuation + vilanterol 25 microgram/actuation inhalation: powder for, 30 actuations

<table>
<thead>
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<th>Premium $</th>
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<tr>
<td>Anoro Ellipta 62.5/25 [GK]</td>
<td>96.38</td>
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</table>

**OTHER DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, INHALANTS**

### Glucocorticoids

**BECLOMETHASONE**

beclomethasone dipropionate 100 microgram/actuation inhalation: pressurised, 200

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Premium $</th>
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<tbody>
<tr>
<td>Qvar 100 [IA]</td>
<td>33.80</td>
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<td>Qvar 50 [IA]</td>
<td>19.63</td>
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Restricted benefit

Patients unable to achieve co-ordinated use of other metered dose inhalers containing this drug

**BECLOMETHASONE DIPROPIONATE** Oral pressurised inhalation in breath actuated device 100 micrograms per dose (200 doses), CFC-free formulation, 1

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN</th>
</tr>
</thead>
<tbody>
<tr>
<td>Qvar 100 Autohaler [IA]</td>
<td>39.47</td>
<td>37.70</td>
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</table>

**BECLOMETHASONE DIPROPIONATE** Oral pressurised inhalation in breath actuated device 50 micrograms per dose (200 doses), CFC-free formulation, 1

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Premium $</th>
<th>DPMQ $</th>
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<tbody>
<tr>
<td>Qvar 50 Autohaler [IA]</td>
<td>28.21</td>
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**BUDESONIDE**

budesonide 100 microgram/actuation inhalation: powder for, 200 actuations

<table>
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<tr>
<th>Brand Name and Manufacturer</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pulmicort Turbuhaler [AP]</td>
<td>23.68</td>
<td>24.83</td>
<td></td>
</tr>
<tr>
<td>Pulmicort Respules [AP]</td>
<td>49.34</td>
<td>37.70</td>
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</table>

budesonide 200 microgram/actuation inhalation: powder for, 200 actuations

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN</th>
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<tbody>
<tr>
<td>Pulmicort Turbuhaler [AP]</td>
<td>23.68</td>
<td>24.83</td>
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<tr>
<td>Pulmicort Respules [AP]</td>
<td>49.34</td>
<td>37.70</td>
<td></td>
</tr>
</tbody>
</table>

budesonide 400 microgram/actuation inhalation: powder for, 200 actuations

<table>
<thead>
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<tr>
<td>Pulmicort Turbuhaler [AP]</td>
<td>46.18</td>
<td>37.70</td>
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**BUDESONIDE**

Authority required (STREAMLINED) 1351

Severe chronic asthma in patients who require long-term steroid therapy and who are unable to use other forms of inhaled steroid therapy

budesonide 1 mg/2 mL inhalation: solution, 30 x 2 mL ampoules

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN</th>
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</thead>
<tbody>
<tr>
<td>Pulmicort Respules [AP]</td>
<td>49.34</td>
<td>37.70</td>
<td></td>
</tr>
</tbody>
</table>

budesonide 500 microgram/2 mL inhalation: solution, 30 x 2 mL ampoules

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pulmicort Respules [AP]</td>
<td>38.20</td>
<td>37.70</td>
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**CICLESONIDE**

ciclesonide 160 microgram/actuation inhalation: pressurised, 120 actuations

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN</th>
</tr>
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<tbody>
<tr>
<td>Alvesco 160 [NQ]</td>
<td>42.59</td>
<td>37.70</td>
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## RESPIRATORY SYSTEM

### General

Table:

<table>
<thead>
<tr>
<th>Drug Name and Manufacturer</th>
<th>Maximum Quantity</th>
<th>Packs</th>
<th>N° of Rpts</th>
<th>Premium ($)</th>
<th>DPMO ($)</th>
<th>MRVSN ($)</th>
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<tbody>
<tr>
<td>Fluticasone propionate 80 microgram/actuation inhalation: pressurised, 120 actuations</td>
<td>8853Y</td>
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<td>..</td>
<td>26.49</td>
<td>27.64</td>
<td>Alvesco 80 [NQ]</td>
</tr>
<tr>
<td>Fluticasone propionate 100 microgram/actuation inhalation: powder for, 60 actuations</td>
<td>8147T</td>
<td>5</td>
<td>..</td>
<td>17.43</td>
<td>18.58</td>
<td>Flixotide Junior Accuhaler [GK]</td>
</tr>
<tr>
<td>Fluticasone propionate 125 microgram/actuation inhalation: pressurised, 120 actuations</td>
<td>8345F</td>
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<td>..</td>
<td>31.00</td>
<td>32.15</td>
<td>Flixotide [GK]</td>
</tr>
<tr>
<td>Fluticasone propionate 250 microgram/actuation inhalation: powder for, 60 actuations</td>
<td>8148W</td>
<td>5</td>
<td>..</td>
<td>31.00</td>
<td>32.15</td>
<td>Flixotide Accuhaler [GK]</td>
</tr>
<tr>
<td>Fluticasone propionate 250 microgram/actuation inhalation: pressurised, 120 actuations</td>
<td>8346G</td>
<td>5</td>
<td>..</td>
<td>50.06</td>
<td>37.70</td>
<td>Flixotide Accuhaler [GK]</td>
</tr>
<tr>
<td>Fluticasone propionate 50 microgram/actuation inhalation: pressurised, 120</td>
<td>8516F</td>
<td>5</td>
<td>..</td>
<td>17.43</td>
<td>18.58</td>
<td>Flixotide Junior [GK]</td>
</tr>
<tr>
<td>Fluticasone propionate 500 microgram/actuation inhalation: powder for, 60 actuations</td>
<td>8149X</td>
<td>5</td>
<td>..</td>
<td>50.06</td>
<td>37.70</td>
<td>Flixotide Accuhaler [GK]</td>
</tr>
</tbody>
</table>

### Anticholinergics

#### Aclidinium

- **Restricted benefit**

  Chronic obstructive pulmonary disease (COPD)

  | Aclidinium 322 microgram/actuation inhalation: powder for, 60 actuations | 10124W | 5 | .. | 62.73 | 37.70 | Bretaris Genuair [FK] |

#### Glycopyrronium

- **Restricted benefit**

  Chronic obstructive pulmonary disease (COPD)

  | Glycopyrronium 50 microgram inhalation, 30 capsules | 10059K | 5 | .. | 62.73 | 37.70 | seebri breezhaler [NV] |

#### Ipratropium

- Asthma in patients unable to use this drug delivered from an oral pressurised inhalation device via a spacer

  | Ipratropium bromide 20 microgram/actuation inhalation: pressurised, 200 actuations | 8671J | 5 | .. | *34.18 | 35.33 | Atrovent [BY] |

- Chronic obstructive pulmonary disease in patients unable to use this drug delivered from an oral pressurised inhalation device via a spacer

  | Ipratropium bromide 250 microgram/mL inhalation: solution, 30 x 1 mL ampoules | 1542E | 5 | .. | *28.28 | 29.43 | Aeron 250 [QA] |

  | APO-Ipratropium [TX] | 0.52 | *28.80 | 29.43 | * Atrovent [BY] |
### RESPIRATORY SYSTEM

#### ipratropium bromide 500 microgram/mL inhalation: solution, 30 x 1 mL ampoules

<table>
<thead>
<tr>
<th>8238N</th>
<th>Max.Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMO $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>*Aeron 500 [QA]</td>
<td>* Ipratropium [AF]</td>
</tr>
</tbody>
</table>

#### Tiotropium

**Restricted benefit**

Chronic obstructive pulmonary disease

| 8626B | Max.Qty Packs | No. of Rpts | Premium $ | DPMO $ | MRVSN $ | Brand Name and Manufacturer |
|-------|---------------|-------------|-----------|---------|----------|----------------------------|----------------------------|
|       |               |             |           |         |          | Spiriva [BY]                |

#### Umeclidinium

**Restricted benefit**

Chronic obstructive pulmonary disease (COPD)

| 10187E | Max.Qty Packs | No. of Rpts | Premium $ | DPMO $ | MRVSN $ | Brand Name and Manufacturer |
|--------|---------------|-------------|-----------|---------|----------|----------------------------|----------------------------|
| ‡1     | 5             |             | 62.73     | 37.70   |          | Incruse Ellipta [GK]       |

#### Cromoglycate, excl. corticosteroids

| 8767K  | Max.Qty Packs | No. of Rpts | Premium $ | DPMO $ | MRVSN $ | Brand Name and Manufacturer |
|--------|---------------|-------------|-----------|---------|----------|----------------------------|----------------------------|
| ‡1     | 5             |             | 33.84     | 34.99   |          | Intal CFC-Free [SW]        |

| 2878L  | Max.Qty Packs | No. of Rpts | Premium $ | DPMO $ | MRVSN $ | Brand Name and Manufacturer |
|--------|---------------|-------------|-----------|---------|----------|----------------------------|----------------------------|
|       |               |             | 31.75     | 32.90   |          | Intal Spincaps [GN]        |

| 8334P  | Max.Qty Packs | No. of Rpts | Premium $ | DPMO $ | MRVSN $ | Brand Name and Manufacturer |
|--------|---------------|-------------|-----------|---------|----------|----------------------------|----------------------------|
| ‡1     | 5             |             | 38.65     | 37.70   |          | Intal Forte CFC-Free [SW]  |

#### Nedocromil

| 8365G  | Max.Qty Packs | No. of Rpts | Premium $ | DPMO $ | MRVSN $ | Brand Name and Manufacturer |
|--------|---------------|-------------|-----------|---------|----------|----------------------------|----------------------------|
| ‡1     | 5             |             | 40.20     | 37.70   |          | Tilade CFC-Free [SW]       |

### ADRENERGICS FOR SYSTEMIC USE

#### Alpha- and beta-adrenoreceptor agonists

#### Adrenaline

| 1016L  | Max.Qty Packs | No. of Rpts | Premium $ | DPMO $ | MRVSN $ | Brand Name and Manufacturer |
|--------|---------------|-------------|-----------|---------|----------|----------------------------|----------------------------|
|       |               |             | 20.68     | 21.83   |          | Link Medical Products Pty Ltd [LM] |

| 5004J  | Max.Qty Packs | No. of Rpts | Premium $ | DPMO $ | MRVSN $ | Brand Name and Manufacturer |
|--------|---------------|-------------|-----------|---------|----------|----------------------------|----------------------------|
|       |               |             | 20.68     | 21.83   |          | Link Medical Products Pty Ltd [LM] |

### Adrenaline

**Caution**

EpiPen and Anapen products have different administration techniques and should not be prescribed to the same patient without training in their use.

**Authority required**

Acute allergic reaction with anaphylaxis

**Clinical criteria:**

Patient must have been assessed to be at significant risk of anaphylaxis by, or in consultation with a clinical immunologist; OR

Schedule of Pharmaceutical Benefits 523
Patient must have been assessed to be at significant risk of anaphylaxis by, or in consultation with an allergist; OR
Patient must have been assessed to be at significant risk of anaphylaxis by, or in consultation with a paediatrician; OR
Patient must have been assessed to be at significant risk of anaphylaxis by, or in consultation with a respiratory physician.

The name of the specialist consulted must be provided at the time of application for initial supply.

**Authority required**
Acute allergic reaction with anaphylaxis
Treatment Phase: Initial sole PBS-subsidised supply for anticipated emergency treatment

**Clinical criteria:**
Patient must have been discharged from hospital or an emergency department after treatment with adrenaline for acute allergic reaction with anaphylaxis.

**Authority required**
Acute allergic reaction with anaphylaxis
Treatment Phase: Continuing sole PBS-subsidised supply for anticipated emergency treatment

**Clinical criteria:**
Patient must have previously been issued with an authority prescription for this drug.

**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.)

Authority approvals will be limited to a maximum quantity of 2 auto-injectors (Anapen or EpiPen) at any one time.

No applications for repeats will be authorised.

### adrenaline 150 microgram/0.3 mL injection, 1 x 0.3 mL syringe

<table>
<thead>
<tr>
<th>Code</th>
<th>Max Qty</th>
<th>Packs</th>
<th>No of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
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<th>Brand Name and Manufacturer</th>
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<tr>
<td>3408J</td>
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<td>..</td>
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<td>106.34</td>
<td>37.70</td>
<td></td>
<td>Anapen Junior [LM]</td>
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</table>

### adrenaline 150 microgram/0.3 mL injection, 1 x 0.3 mL syringe

<table>
<thead>
<tr>
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<th>Max Qty</th>
<th>Packs</th>
<th>No of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
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<tr>
<td>8697R</td>
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<td>..</td>
<td>106.34</td>
<td>37.70</td>
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<td>EpiPen Jr. [AL]</td>
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</table>

### adrenaline 300 microgram/0.3 mL injection, 1 x 0.3 mL syringe

<table>
<thead>
<tr>
<th>Code</th>
<th>Max Qty</th>
<th>Packs</th>
<th>No of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
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<tbody>
<tr>
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<td>..</td>
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<td>106.34</td>
<td>37.70</td>
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<td>Anapen [LM]</td>
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</table>

### adrenaline 300 microgram/0.3 mL injection, 1 x 0.3 mL syringe

<table>
<thead>
<tr>
<th>Code</th>
<th>Max Qty</th>
<th>Packs</th>
<th>No of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>8698T</td>
<td>1</td>
<td>..</td>
<td>..</td>
<td>106.34</td>
<td>37.70</td>
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<td>EpiPen [AL]</td>
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</table>

**Selective beta-2-adrenoreceptor agonists**

### SALBUTAMOL

**salbutamol 2 mg/5 mL oral liquid, 150 mL**

<table>
<thead>
<tr>
<th>Code</th>
<th>Max Qty</th>
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<th>No of Rpts</th>
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<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>1103C</td>
<td>2</td>
<td>5</td>
<td>..</td>
<td>22.54</td>
<td>23.69</td>
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<td>Ventolin [GK]</td>
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</table>

### TERBUTALINE

**terbutaline sulfate 500 microgram/mL injection, 5 x 1 mL ampoules**

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<tr>
<th>Code</th>
<th>Max Qty</th>
<th>Packs</th>
<th>No of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>1034K</td>
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<td>..</td>
<td>30.93</td>
<td>32.08</td>
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<td>Bricanyl [AP]</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.
### RESPIRATORY SYSTEM

#### theophylline 133.3 mg/25 mL oral liquid, 500 mL

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<td>..</td>
<td>12.65</td>
<td>13.80</td>
<td>Nuelin [IA]</td>
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</table>

#### theophylline 200 mg tablet: modified release, 100 tablets

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<th>Max-Qty Packs</th>
<th>No. of Rpts</th>
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<th>DPMQ ($)</th>
<th>MRVSN ($)</th>
<th>Brand Name and Manufacturer</th>
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<td>12.50</td>
<td>13.65</td>
<td>Nuelin-SR 200 [IA]</td>
</tr>
</tbody>
</table>

#### theophylline 250 mg tablet: modified release, 100 tablets

<table>
<thead>
<tr>
<th>Code</th>
<th>Max-Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium ($)</th>
<th>DPMQ ($)</th>
<th>MRVSN ($)</th>
<th>Brand Name and Manufacturer</th>
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<tr>
<td>2634P</td>
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<td>13.66</td>
<td>14.81</td>
<td>Nuelin-SR 250 [IA]</td>
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#### theophylline 300 mg tablet: modified release, 100 tablets

<table>
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<tr>
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<th>No. of Rpts</th>
<th>Premium ($)</th>
<th>DPMQ ($)</th>
<th>MRVSN ($)</th>
<th>Brand Name and Manufacturer</th>
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<tr>
<td>8231F</td>
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<td>15.04</td>
<td>16.19</td>
<td>Nuelin-SR 300 [IA]</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.

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

#### montelukast 4 mg tablet: chewable, 28

<table>
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<tr>
<th>Code</th>
<th>Max-Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium ($)</th>
<th>DPMQ ($)</th>
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<td>32.03</td>
<td>33.18</td>
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<td></td>
<td>Montair 4 [GN]</td>
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<td>Montelukast GH [GQ]</td>
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<td></td>
<td>Montelukast Sandoz 4 [SZ]</td>
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<td>Respikast 4 [QA]</td>
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<td>Terry White Chemists Montelukast [TW]</td>
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<td>Auro-Montelukast Tabs 4 [DO]</td>
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<td>Singulair [MK]</td>
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<td></td>
<td>T Lukast [AF]</td>
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</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.

**Authority required (STREAMLINED)**

**3217**

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.

**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.

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

#### montelukast 5 mg tablet: chewable, 28

<table>
<thead>
<tr>
<th>Code</th>
<th>Max-Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium ($)</th>
<th>DPMQ ($)</th>
<th>MRVSN ($)</th>
<th>Brand Name and Manufacturer</th>
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<td>8628D</td>
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<td>..</td>
<td>30.51</td>
<td>31.66</td>
<td>APO-Montelukast [TX]</td>
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<td>Chem mart Montelukast [CH]</td>
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<tr>
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<td></td>
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<td></td>
<td></td>
<td>Montair 5 [GN]</td>
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<td>Montelukast GH [GQ]</td>
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<td>Singulair [MK]</td>
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### SENSORY ORGANS

#### COUGH AND COLD PREPARATIONS

**COUGH SUPPRESSANTS, EXCL. COMBINATIONS WITH EXPECTORANTS**

*Opium alkaloids and derivatives*

<table>
<thead>
<tr>
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</thead>
<tbody>
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<td>Max Qty</td>
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<td>1214X</td>
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#### ANTICHOLINERGICS

*Anticholinergic agents*

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<tr>
<th>Promethazine hydrochloride 50 mg/2 mL injection, 5 x 2 mL ampoules</th>
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</thead>
<tbody>
<tr>
<td>Max Qty</td>
</tr>
<tr>
<td>1948M</td>
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<td></td>
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</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>Azithromycin 200 mg/5 mL oral liquid: powder for, 15 mL</th>
</tr>
</thead>
<tbody>
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<td>Max Qty</td>
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<tr>
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<table>
<thead>
<tr>
<th>Azithromycin 500 mg tablet, 2</th>
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<td>8336R</td>
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**Chloramphenicol**

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<tr>
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<tr>
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<table>
<thead>
<tr>
<th>Chloramphenicol 0.5% eye drops, 10 mL</th>
</tr>
</thead>
<tbody>
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<td>5055C</td>
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<table>
<thead>
<tr>
<th>Chloramphenicol 0.5% eye drops, 10 mL</th>
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<tbody>
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<table>
<thead>
<tr>
<th>Chloramphenicol 1% eye ointment, 4 g</th>
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<tbody>
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<td>1171P</td>
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### Chloramphenicol 1% Eye Ointment, 4 g

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<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>†1</td>
<td>..</td>
<td>..</td>
<td>10.10</td>
<td>11.25</td>
<td>Chlorisig [QA]</td>
<td></td>
</tr>
</tbody>
</table>

### Gentamicin

**Restricted benefit**
- Perioperative use in ophthalmic surgery
- Suspected pseudomonal eye infection

**Gentamicin 0.3% Eye Drops, 5 mL**

<table>
<thead>
<tr>
<th>5566Y</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>†1</td>
<td>2</td>
<td>..</td>
<td>18.63</td>
<td>19.78</td>
<td>Genoptic [AG]</td>
<td></td>
</tr>
</tbody>
</table>

### Tobramycin

**Restricted benefit**
- Perioperative use in ophthalmic surgery
- Suspected pseudomonal eye infection

**Tobramycin 0.3% (3 mg/mL) Eye Drops, 5 mL**

<table>
<thead>
<tr>
<th>5569D</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
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<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>†1</td>
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<td>..</td>
<td>19.62</td>
<td>20.77</td>
<td>Tobrex [AQ]</td>
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</table>

**Tobramycin 0.3% Eye Ointment, 3.5 g**

<table>
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<tr>
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<th>DPMQ $</th>
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<th>Brand Name and Manufacturer</th>
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<tr>
<td>†1</td>
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<td>22.72</td>
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<td>Tobrex [AQ]</td>
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</tr>
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</table>

### Aciclovir

**Restricted benefit**
- Herpes simplex keratitis

**Aciclovir 3% Eye Ointment, 4.5 g**

<table>
<thead>
<tr>
<th>5501M</th>
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<th>Premium $</th>
<th>DPMQ $</th>
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<tbody>
<tr>
<td>†1</td>
<td>..</td>
<td>..</td>
<td>37.80</td>
<td>37.70</td>
<td>Zovirax [GK]</td>
<td></td>
</tr>
</tbody>
</table>
**SENSORY ORGANS**

- **ACICLOVIR**
  
  **Restricted benefit**
  Herpes simplex keratitis

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

  aciclovir 3% eye ointment, 4.5 g

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>†1</td>
<td>..</td>
<td>37.80</td>
<td>37.70</td>
<td>Zovirax [GK]</td>
<td></td>
</tr>
</tbody>
</table>

- **Fluoroquinolones**

  - **CIPROFLOXACIN**
    
    **Authority required**
    Bacterial keratitis
    
    **Treatment criteria:**
    Must be treated by an ophthalmologist or in consultation with an ophthalmologist.

    ciprofloxacin 0.3% eye drops, 5 mL

    | Max Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
    |---------------|-------------|-----------|--------|---------|-----------------------------|
    | 2             | ..          | 28.82     | 29.97  | *2.06   | *30.88 29.97 Ciloxan [AQ]   |

  - **CIPROFLOXACIN**
    
    **Authority required**
    Bacterial keratitis
    
    **Treatment criteria:**
    Must be treated by an ophthalmologist or in consultation with an ophthalmologist.

    ciprofloxacin 0.3% eye drops, 5 mL

    | Max Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
    |---------------|-------------|-----------|--------|---------|-----------------------------|
    | 2             | ..          | 28.82     | 29.97  | *2.06   | *30.88 29.97 Ciloxan [AQ]   |

- **OFLOXACIN**

  **Authority required**
  Bacterial keratitis
  
  **Treatment criteria:**
  Must be treated by an ophthalmologist or in consultation with an ophthalmologist.

  ofloxacin 0.3% (3 mg/mL) eye drops, 5 mL

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>..</td>
<td>35.64</td>
<td>36.79</td>
<td>Ocuflox [AG]</td>
<td></td>
</tr>
</tbody>
</table>

- **OFLOXACIN**

  **Authority required**
  Bacterial keratitis
  
  **Treatment criteria:**
  Must be treated by an ophthalmologist or in consultation with an ophthalmologist.

  ofloxacin 0.3% (3 mg/mL) eye drops, 5 mL

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
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</thead>
<tbody>
<tr>
<td>2</td>
<td>..</td>
<td>35.64</td>
<td>36.79</td>
<td>Ocuflox [AG]</td>
<td></td>
</tr>
</tbody>
</table>

- **ANTIINFLAMMATORY AGENTS**

  - **Corticosteroids, plain**
    
    **DEXAMETHASONE**
    
    **DEXAMETHASONE** Eye drops 1 mg per mL (0.1%), 5 mL, 1

    | Max Qty Packs | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
    |---------------|-------------|-----------|--------|---------|-----------------------------|
    |†1            | 2           | 10.95     | 12.10  | Maxidex [AQ] |

- **DEXAMETHASONE**

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

### DEXAMETHASONE

**Eye drops** 1 mg per mL (0.1%), 5 mL, 1

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>✧1</td>
<td>..</td>
<td>..</td>
<td>10.95</td>
<td>12.10</td>
<td>Maxidex [AQ]</td>
</tr>
</tbody>
</table>

### FLUOROMETHOLONE

**fluorometholone 0.1% eye drops, 5 mL**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tr>
<td>✧1</td>
<td>5</td>
<td>..</td>
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<td>12.10</td>
<td>Flucon [AQ]</td>
<td>FML Liquifilm [AG]</td>
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</table>

### FLUOROMETHOLONE

**fluorometholone 0.1% eye drops, 5 mL**

**Note**

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

### FLUOROMETHOLONE ACETATE

**fluorometholone acetate 0.1% eye drops, 5 mL**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>✧1</td>
<td>2</td>
<td>..</td>
<td>10.95</td>
<td>12.10</td>
<td>Flarex [AQ]</td>
</tr>
</tbody>
</table>

### FLUOROMETHOLONE ACETATE

**fluorometholone acetate 0.1% eye drops, 5 mL**

**Note**

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

### HYDROCORTISONE ACETATE

**hydrocortisone acetate 1% eye ointment, 5 g**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>✧1</td>
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<td>..</td>
<td>13.03</td>
<td>14.18</td>
<td>Hycor [QA]</td>
</tr>
</tbody>
</table>

### HYDROCORTISONE ACETATE

**hydrocortisone acetate 1% eye ointment, 5 g**

**Note**

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

### PHENYLEPHRINE + PREDNISOLONE ACETATE

**Restricted benefit**

Corneal grafts

**Restricted benefit**

Uveitis

**phenylephrine hydrochloride 0.12% + prednisolone acetate 1% eye drops, 10 mL**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>✧1</td>
<td>2</td>
<td>..</td>
<td>26.16</td>
<td>27.31</td>
<td>Prednefrin Forte [AG]</td>
</tr>
</tbody>
</table>

### PHENYLEPHRINE + PREDNISOLONE ACETATE

**Restricted benefit**

Uveitis

**Note**

No applications for increased maximum quantities and/or repeats will be authorised.
phenylephrine hydrochloride 0.12% + prednisolone acetate 1% eye drops, 10 mL

<table>
<thead>
<tr>
<th>Code</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium</th>
<th>DPMQ</th>
<th>MRVSN</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>5568C</td>
<td>1</td>
<td></td>
<td>26.16</td>
<td>27.31</td>
<td></td>
<td>Prednefrin Forte [AG]</td>
</tr>
</tbody>
</table>

Antinflammatory agents, non-steroids

- **FLURBIPROFEN**

flurbiprofen sodium 0.03% (120 microgram/0.4 mL) eye drops, 5 x 0.4 mL ampoules

<table>
<thead>
<tr>
<th>Code</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium</th>
<th>DPMQ</th>
<th>MRVSN</th>
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<td>1</td>
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<td>17.16</td>
<td>18.31</td>
<td></td>
<td>Ocufen [AG]</td>
</tr>
</tbody>
</table>

- **APRACLONIDINE**

  Restricted benefit

  Intra-ocular pressure

  Clinical criteria:

  The treatment must be for short-term reduction of intra-ocular pressure, AND

  Patient must already be on maximally tolerated anti-glaucoma therapy.

apraclonidine 0.5% eye drops, 10 mL

<table>
<thead>
<tr>
<th>Code</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium</th>
<th>DPMQ</th>
<th>MRVSN</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>8083K</td>
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<td></td>
<td>42.11</td>
<td>37.70</td>
<td></td>
<td>Iopidine 0.5% [AQ]</td>
</tr>
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</table>

- **BRIMONIDINE**

brimonidine tartrate 0.15% eye drops, 5 mL

<table>
<thead>
<tr>
<th>Code</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium</th>
<th>DPMQ</th>
<th>MRVSN</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>5298W</td>
<td>1</td>
<td></td>
<td>20.48</td>
<td>21.63</td>
<td></td>
<td>Alphagan P 1.5 [AG]</td>
</tr>
</tbody>
</table>

brimonidine tartrate 0.2% eye drops, 5 mL

<table>
<thead>
<tr>
<th>Code</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium</th>
<th>DPMQ</th>
<th>MRVSN</th>
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<tbody>
<tr>
<td>8351M</td>
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<td>20.48</td>
<td>21.63</td>
<td>1.63</td>
<td>Enidin [PE]</td>
</tr>
</tbody>
</table>

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.

brimonidine tartrate 0.15% eye drops, 5 mL

<table>
<thead>
<tr>
<th>Code</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium</th>
<th>DPMQ</th>
<th>MRVSN</th>
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<tr>
<td>5563T</td>
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<td>20.48</td>
<td>21.63</td>
<td></td>
<td>Alphagan P 1.5 [AG]</td>
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brimonidine tartrate 0.2% eye drops, 5 mL

<table>
<thead>
<tr>
<th>Code</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
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<th>DPMQ</th>
<th>MRVSN</th>
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<tbody>
<tr>
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<td>20.48</td>
<td>21.63</td>
<td>1.63</td>
<td>Enidin [PE]</td>
</tr>
</tbody>
</table>

- **BRIMONIDINE + 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.
**SENSORY ORGANS**

**Schedule of Pharmaceutical Benefits**

<table>
<thead>
<tr>
<th>brimonidine tartrate 0.2% + timolol 0.5% eye drops, 5 mL</th>
</tr>
</thead>
<tbody>
<tr>
<td>8826M</td>
</tr>
<tr>
<td>Max Qty Packs</td>
</tr>
<tr>
<td>†1</td>
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</tbody>
</table>

**BRIMONIDINE + TIMOLOL**

*Restricted benefit*

**Clinical criteria:**
- The condition must have been inadequately controlled with monotherapy, **AND**
- Patient must have open-angle glaucoma; **OR**
- Patient must have ocular hypertension.

**Note**

*Shared Care Model:*
- For prescribing by optometrists where care of a patient is shared between an optometrist and ophthalmologist in a formalised arrangement with an agreed management plan. Further information can be found in the Guidelines for Shared Care of Glaucoma Patients.

<table>
<thead>
<tr>
<th>brimonidine tartrate 0.2% + timolol 0.5% eye drops, 5 mL</th>
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</thead>
<tbody>
<tr>
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<tr>
<td>Max Qty Packs</td>
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<td>†1</td>
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**Parasympathomimetics**

**PILOCARPINE**

<table>
<thead>
<tr>
<th>pilocarpine hydrochloride 1% eye drops, 15 mL</th>
</tr>
</thead>
<tbody>
<tr>
<td>2595N</td>
</tr>
<tr>
<td>Max Qty Packs</td>
</tr>
<tr>
<td>†1</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>pilocarpine hydrochloride 2% eye drops, 15 mL</th>
</tr>
</thead>
<tbody>
<tr>
<td>2596P</td>
</tr>
<tr>
<td>Max Qty Packs</td>
</tr>
<tr>
<td>†1</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>pilocarpine hydrochloride 4% eye drops, 15 mL</th>
</tr>
</thead>
<tbody>
<tr>
<td>2598R</td>
</tr>
<tr>
<td>Max Qty Packs</td>
</tr>
<tr>
<td>†1</td>
</tr>
</tbody>
</table>

**PILOCARPINE**

**Note**

*Shared Care Model:*
- For prescribing by optometrists where care of a patient is shared between an optometrist and ophthalmologist in a formalised arrangement with an agreed management plan. Further information can be found in the Guidelines for Shared Care of Glaucoma Patients.

<table>
<thead>
<tr>
<th>pilocarpine hydrochloride 1% eye drops, 15 mL</th>
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</thead>
<tbody>
<tr>
<td>5536J</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>pilocarpine hydrochloride 2% eye drops, 15 mL</th>
</tr>
</thead>
<tbody>
<tr>
<td>5537K</td>
</tr>
<tr>
<td>Max Qty Packs</td>
</tr>
<tr>
<td>†1</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>pilocarpine hydrochloride 4% eye drops, 15 mL</th>
</tr>
</thead>
<tbody>
<tr>
<td>5538L</td>
</tr>
<tr>
<td>Max Qty Packs</td>
</tr>
<tr>
<td>†1</td>
</tr>
</tbody>
</table>

**Carbonic anhydrase inhibitors**

**ACETAZOLAMIDE**

**Note**

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

**acetzolamide 250 mg tablet, 100**

<table>
<thead>
<tr>
<th>1004W</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Diamox [QA]</td>
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</tbody>
</table>

**BRINZOLAMIDE**

**brinzolamide 1% eye drops, 5 mL**

<table>
<thead>
<tr>
<th>8483L</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>†1</td>
<td>5</td>
<td>23.11</td>
<td>24.26</td>
<td></td>
<td>* BrinzoQuin [IQ]</td>
</tr>
<tr>
<td></td>
<td>†1,18</td>
<td></td>
<td>24.29</td>
<td>24.26</td>
<td></td>
<td>* Azaopt [AQ]</td>
</tr>
</tbody>
</table>

**BRINZOLAMIDE**

**brinzolamide 1% eye drops, 5 mL**

<table>
<thead>
<tr>
<th>5540N</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
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</thead>
<tbody>
<tr>
<td>†1</td>
<td>5</td>
<td>.</td>
<td>23.11</td>
<td>24.26</td>
<td></td>
<td>* BrinzoQuin [IQ]</td>
</tr>
<tr>
<td>†1,18</td>
<td></td>
<td></td>
<td>24.29</td>
<td>24.26</td>
<td></td>
<td>* Azaopt [AQ]</td>
</tr>
</tbody>
</table>

**BRINZOLAMIDE + TIMOLOL**

**Restricted benefit**
Elevated intra-ocular pressure

**Clinical criteria:**
The condition must have been inadequately controlled with monotherapy, **AND**

Patient must have open-angle glaucoma; **OR**

Patient must have ocular hypertension.

**brinzolamide 1% + timolol 0.5% eye drops, 5 mL**

<table>
<thead>
<tr>
<th>3438Y</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
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<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>†1</td>
<td>5</td>
<td>.</td>
<td>27.22</td>
<td>28.37</td>
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<td>Azarga [AQ]</td>
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</tbody>
</table>

**BRINZOLAMIDE + TIMOLOL**

**Restricted benefit**
Elevated intra-ocular pressure

**Clinical criteria:**
The condition must have been inadequately controlled with monotherapy, **AND**

Patient must have open-angle glaucoma; **OR**

Patient must have ocular hypertension.

**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.

**brinzolamide 1% + timolol 0.5% eye drops, 5 mL**

<table>
<thead>
<tr>
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<th>Max Qty Packs</th>
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**DORZOLAMIDE**

**dorzolamide 2% (20 mg/mL) eye drops, 5 mL**

<table>
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<tr>
<td>†1</td>
<td>5</td>
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<td>19.26</td>
<td>20.41</td>
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<td>* Trusopt [MK]</td>
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**DORZOLAMIDE**

**Note**
Shared Care Model:
For prescribing by optometrists where care of a patient is shared between an optometrist and ophthalmologist in a formalised arrangement with an agreed management plan. Further information can be found in the Guidelines for Shared Care of Glaucoma Patients.
dorzolamide 2% (20 mg/mL) eye drops, 5 mL

<table>
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<tr>
<th>Max.Qty Packs</th>
<th>No. of Rpts</th>
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<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
<th>Brand Name and Manufacturer</th>
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<tr>
<td>†1</td>
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<td>19.26</td>
<td>20.41</td>
<td>* Trusamide [QA]</td>
<td>* Trusopt [MK]</td>
</tr>
</tbody>
</table>

**DORZOLAMIDE + TIMOLOL**

**Restricted benefit**
Elevated intra-ocular pressure

**Clinical criteria:**
The condition must have been inadequately controlled with monotherapy, **AND**
Patient must have open-angle glaucoma; **OR**
Patient must have ocular hypertension.

### dorzolamide 2% + timolol 0.5% eye drops, 5 mL

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
<th>No. of Rpts</th>
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<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>†1</td>
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<td>25.34</td>
<td>* Cosdor [QA]</td>
<td>* Dorzolamide/Timolol Sandoz 20/5 [SZ]</td>
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</table>

### dorzolamide 2% + timolol 0.5% eye drops, 5 mL

<table>
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<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>†1</td>
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<td>25.34</td>
<td>* Cosopt [MK]</td>
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**Beta blocking agents1)**

### BETAXOLOL

**betaxolol 0.25% eye drops, 5 mL**

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<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
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<td>15.11</td>
<td>16.26</td>
<td>Betoptic S [AQ]</td>
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</tbody>
</table>

**betaxolol 0.5% eye drops, 5 mL**

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
<th>No. of Rpts</th>
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<th>DPMQ $</th>
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<tr>
<td>†1</td>
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<td>..</td>
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<td>16.26</td>
<td>* BetoQuin [IQ]</td>
</tr>
</tbody>
</table>

**BETAXOLOL**

**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.

**betaxolol 0.25% eye drops, 5 mL**

<table>
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<tr>
<th>Max.Qty Packs</th>
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</tr>
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**betaxolol 0.5% eye drops, 5 mL**

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<td>16.26</td>
<td>* BetoQuin [IQ]</td>
</tr>
</tbody>
</table>

---

1) Beta blocking agents

---

**SENSORY ORGANS**

Schedule of Pharmaceutical Benefits 533
### TIMOLOL

**timolol 0.1% eye gel, 5 g**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>†1</td>
<td>5</td>
<td>..</td>
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<td>14.36</td>
<td>Nyogel [AS]</td>
</tr>
</tbody>
</table>

**timolol 0.25% (2.5 mg/mL) eye drops, 2.5 mL**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>†1</td>
<td>5</td>
<td>..</td>
<td>11.88</td>
<td>13.03</td>
<td>Timoptol XE [MK]</td>
</tr>
</tbody>
</table>

**timolol 0.5% (5 mg/mL) eye drops, 2.5 mL**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
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</thead>
<tbody>
<tr>
<td>†1</td>
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**timolol 0.5% (5 mg/mL) eye drops, 5 mL**

<table>
<thead>
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<td>†1</td>
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<td>15.68</td>
<td>13.80</td>
<td>* Timoptol [FR]</td>
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</table>

### 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.

**timolol 0.1% eye gel, 5 g**

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**timolol 0.25% (2.5 mg/mL) eye drops, 2.5 mL**

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</tbody>
</table>

**timolol 0.5% (5 mg/mL) eye drops, 2.5 mL**

<table>
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<tr>
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**timolol 0.5% (5 mg/mL) eye drops, 5 mL**

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<td>3.03</td>
<td>15.68</td>
<td>13.80</td>
<td>* Timoptol [FR]</td>
</tr>
</tbody>
</table>

### Prostaglandin analogues

**BIMATOPROST**

**bimatoprost 0.03% eye drops, 3 mL**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>†1</td>
<td>5</td>
<td>..</td>
<td>42.48</td>
<td>37.70</td>
<td>Lumigan [AG]</td>
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</tbody>
</table>

**bimatoprost 0.03% eye drops, 30 x 0.4 mL unit doses**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>†1</td>
<td>5</td>
<td>..</td>
<td>36.91</td>
<td>37.70</td>
<td>Lumigan PF [AG]</td>
</tr>
</tbody>
</table>

### 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.

**bimatoprost 0.03% eye drops, 3 mL**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>†1</td>
<td>5</td>
<td>..</td>
<td>42.48</td>
<td>37.70</td>
<td>Lumigan [AG]</td>
</tr>
</tbody>
</table>
bimatoprost 0.03% eye drops, 30 x 0.4 mL unit doses

<table>
<thead>
<tr>
<th>Code</th>
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<th>No. of Rpts</th>
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<td>36.91</td>
<td>37.70</td>
<td>Lumigan PF [AG]</td>
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</tbody>
</table>

**BIMATOPROST + TIMOLOL**

**Restricted benefit**

Elevated intra-ocular pressure

**Clinical criteria:**
The condition must have been inadequately controlled with monotherapy, **AND**

- Patient must have open-angle glaucoma; OR
- Patient must have ocular hypertension.

bimatoprost 0.03% + timolol 0.5% eye drops, 30 x 0.4 mL unit doses

<table>
<thead>
<tr>
<th>Code</th>
<th>Max Qty Packs</th>
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<td>41.21</td>
<td>37.70</td>
<td>GANfort PF 0.3/5 [AG]</td>
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**BIMATOPROST + TIMOLOL**

**Restricted benefit**

Elevated intra-ocular pressure

**Clinical criteria:**
The condition must have been inadequately controlled with monotherapy, **AND**

- Patient must have open-angle glaucoma; OR
- Patient must have ocular hypertension.

bimatoprost 0.03% + timolol 0.5% eye drops, 3 mL

<table>
<thead>
<tr>
<th>Code</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
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</tbody>
</table>

**BIMATOPROST + TIMOLOL**

**Restricted benefit**

Elevated intra-ocular pressure

**Clinical criteria:**
The condition must have been inadequately controlled with monotherapy, **AND**

- Patient must have open-angle glaucoma; OR
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**Note**

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bimatoprost 0.03% + timolol 0.5% eye drops, 3 mL

<table>
<thead>
<tr>
<th>Code</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
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<td>46.94</td>
<td>37.70</td>
<td>Ganfort 0.3/5 [AG]</td>
</tr>
</tbody>
</table>

bimatoprost 0.03% + timolol 0.5% eye drops, 30 x 0.4 mL unit doses

<table>
<thead>
<tr>
<th>Code</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
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<td>37.70</td>
<td>GANfort PF 0.3/5 [AG]</td>
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</table>

**LATANOPROST**

Latanoprost 0.005% eye drops, 2.5 mL

<table>
<thead>
<tr>
<th>Code</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
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<th>DPMQ $</th>
<th>MRVSN $</th>
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<td>5</td>
<td>..</td>
<td>24.06</td>
<td>25.21</td>
<td>* APO-Latanoprost [TX]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Latanoprost Actavis [GN]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Latanoprost Pfizer [FZ]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Terry White Chemists</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Latanoprost [TW]</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Xalatan [PF]</td>
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<td>* Chem Mart Latanoprost [CH]</td>
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<td></td>
<td></td>
<td>* Latanoprost GH [GQ]</td>
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<tr>
<td></td>
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<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>* Xalaprost [QA]</td>
</tr>
</tbody>
</table>

**LATANOPROST**

**Note**

**Shared Care Model:**

For prescribing by optometrists where care of a patient is shared between an optometrist and ophthalmologist in a formalised arrangement with an agreed management plan. Further information can be found in the Guidelines for Shared Care of Glaucoma Patients.
**SENSORY ORGANS**

### SENSORY ORGANS

#### latanoprost 0.005% eye drops, 2.5 mL

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
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<tr>
<td>‡1</td>
<td>5</td>
<td>..</td>
<td>24.06</td>
<td>25.21</td>
</tr>
</tbody>
</table>

- **Brand Name and Manufacturer**
  - APO-Latanoprost [TX]
  - Latanoprost Actavis [SN]
  - Latanoprost Pfizer [FZ]
  - Terry White Chemists Latanoprost [TW]
  - Xalatan [PF]

#### 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.

### Latanoprost 0.005% + timolol 0.5% eye drops, 2.5 mL

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
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<td>5</td>
<td>..</td>
<td>41.21</td>
<td>37.70</td>
</tr>
</tbody>
</table>

- **Brand Name and Manufacturer**
  - APO-Latanoprost/Timolol 0.05/5 [TX]
  - Latanoprost/Timolol Sandoz 50/5 [SZ]
  - Xalacom [PF]

#### 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.

### Latanoprost 0.005% + timolol 0.5% eye drops, 2.5 mL

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
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- **Brand Name and Manufacturer**
  - APO-Latanoprost/Timolol 0.05/5 [TX]
  - Latanoprost/Timolol Sandoz 50/5 [SZ]
  - 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 0.0015% eye drops, 30 x 0.3 mL unit doses

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
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</table>

- **Brand Name and Manufacturer**
  - Saflutan [MK]

#### 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 0.0015% eye drops, 30 x 0.3 mL unit doses

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
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<td>‡1</td>
<td>5</td>
<td>..</td>
<td>34.16</td>
<td>35.31</td>
</tr>
</tbody>
</table>

- **Brand Name and Manufacturer**
  - Saflutan [MK]

#### TIMOLOL + TRAVOPROST

**Restricted benefit**

**Elevated intra-ocular pressure**

**Clinical criteria:**

SENSORY ORGANS

Schedule of Pharmaceutical Benefits

The condition must have been inadequately controlled with monotherapy, AND
Patient must have open-angle glaucoma; OR
Patient must have ocular hypertension.

timolol 0.5% + travoprost 0.004% eye drops, 2.5 mL
9057Q

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
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<th>DPMO</th>
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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.
  - **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.

travoprost 0.004% (40 microgram/mL) eye drops, 2.5 mL
8597L

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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.

tratoprost 0.004% (40 microgram/mL) eye drops, 2.5 mL
5555H

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<td>42.48</td>
<td>37.70</td>
<td>Travatan [AQ]</td>
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- **MYDRIATICS AND CYCLOPLERICS**
  - **Anticholinergics**

- **ATROPINE**
  - **ATROPINE Eye drops containing atropine sulfate 10 mg per mL (1%), 15 mL, 1**
1093M

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- **HOMATROPINE**
  - **homatropine hydrobromide 2% eye drops, 15 mL**
10063P

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- **homatropine hydrobromide 2% eye drops, 15 mL**
2541R

<table>
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<td>..</td>
<td>19.15</td>
<td>20.30</td>
<td>Isopto Homatropine [AQ]</td>
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- **DECONGESTANTS AND ANTIALLERGICS**
  - **Other antiallergics**

- **CROMOGLYCATE**
  - **Restricted benefit**
    - Vernal kerato-conjunctivitis
**SENSORY ORGANS**

**cromoglycate sodium 2% eye drops, 10 mL**

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
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**cromoglycate sodium 2% eye drops, 10 mL**

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<tr>
<th>Brand Name and Manufacturer</th>
<th>Max Qty Packs</th>
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<td>Opticrom [SW]</td>
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</table>

**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.

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

Prescribing information (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**
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.

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).

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

Special Pricing Arrangements apply.
**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.

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Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826

HOBART TAS 7001

**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 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).

Special Pricing Arrangements apply.

Pharmaceutical benefits that have the form ranibizumab 0.165 mL injection syringe and pharmaceutical benefits that have the form ranibizumab 0.23 mL injection vial are equivalent for the purposes of substitution.

**ranibizumab 1.65 mg/0.165 mL injection, 1 x 0.165 mL syringe**

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<th>Max Qty Packs</th>
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**ranibizumab 2.3 mg/0.23 mL injection, 1 x 0.23 mL vial**

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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.

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**

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)
verteporfin 15 mg injection, 1 x 15 mg vial

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<tr>
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**OTHER OPHTHALMOLOGICALS**

*Other ophthalmologicals*

- **CARBOMER-974**
  
  **Authority required**
  
  Severe dry eye syndrome in patients who are sensitive to preservatives in multi-dose eye drops

- **CARBOMER-974 0.3% eye gel, 30 x 500 mg unit doses**
  
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<th>Premium $</th>
<th>DPMQ $</th>
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<tr>
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- **CARBOMER-974**
  
  **Authority required (STREAMLINED)**  
  
  1359
  
  Severe dry eye syndrome in patients who are sensitive to preservatives in multi-dose eye drops

- **CARBOMER-974 0.3% eye gel, 30 x 500 mg unit doses**
  
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<td>5</td>
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<td>*36.40</td>
<td>37.55</td>
<td>Poly Gel [AQ]</td>
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</table>

- **CARBOMER-980**
  
  **Restricted benefit**
  
  Severe dry eye syndrome, including Sjogren’s syndrome

- **CARBOMER-980 0.2% eye gel, 10 g**
  
<table>
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<th>No. of Rpts</th>
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  | 1.84    | 1.84  | 11.84       | 11.15     | *Viscotears [AQ]             |                             |

- **CARBOMER-980 0.2% eye gel, 10 g**
  
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</table>
  
  | 1.84    | 1.84  | 11.84       | 11.15     | *Viscotears [AQ]             |                             |

- **CARBOMER-980**
  
  **Authority required**
  
  Severe dry eye syndrome in patients who are sensitive to preservatives in multi-dose eye drops

- **CARBOMER-980 0.2% (2 mg/g) eye drops, 30 x 0.6 mL unit doses**
  
<table>
<thead>
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<th>DPMQ $</th>
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- **CARBOMER-980**
  
  **Authority required (STREAMLINED)**
  
  1359
  
  Severe dry eye syndrome in patients who are sensitive to preservatives in multi-dose eye drops

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<td>5</td>
<td>..</td>
<td>*36.43</td>
<td>37.58</td>
<td>Viscotears Gel PF [AQ]</td>
<td></td>
</tr>
</tbody>
</table>

- **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 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.

- **CARBOMER-980 0.2% eye gel, 10 g**
  
<table>
<thead>
<tr>
<th>Max Qty</th>
<th>Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>1</td>
<td>11</td>
<td>..</td>
<td>10.00</td>
<td>11.15</td>
<td>*Optifresh eye gel [PP]</td>
<td>*PAA [IQ]</td>
</tr>
</tbody>
</table>
  
  | 1.84    | 1.84  | 11.84       | 11.15     | *Viscotears [AQ]             |                             |
### CARAMELLOSE SODIUM

#### Restricted benefit

Severe dry eye syndrome, including Sjogren’s syndrome

<table>
<thead>
<tr>
<th></th>
<th>Max Qty Packs</th>
<th>No of Rpts</th>
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<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td><strong>CARMELLOSE SODIUM</strong> 1% (10 mg/mL) eye drops, 15 mL</td>
<td>5508X</td>
<td>1</td>
<td>5</td>
<td>..</td>
<td>10.93</td>
<td>12.08</td>
</tr>
<tr>
<td><strong>CARMELLOSE SODIUM</strong> 1% (10 mg/mL) eye drops, 15 mL</td>
<td>8593G</td>
<td>1</td>
<td>5</td>
<td>..</td>
<td>10.93</td>
<td>12.08</td>
</tr>
<tr>
<td><strong>CARMELLOSE SODIUM</strong> 0.5% (5 mg/mL) eye drops, 15 mL</td>
<td>5507W</td>
<td>1</td>
<td>5</td>
<td>..</td>
<td>10.93</td>
<td>12.08</td>
</tr>
<tr>
<td><strong>CARMELLOSE SODIUM</strong> 0.5% (5 mg/mL) eye drops, 15 mL</td>
<td>8548X</td>
<td>1</td>
<td>5</td>
<td>..</td>
<td>10.93</td>
<td>12.08</td>
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#### Authority required (STREAMLINED)

1359

Severe dry eye syndrome in patients who are sensitive to preservatives in multi-dose eye drops

<table>
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<tr>
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<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td><strong>CARMELLOSE SODIUM</strong> 1% (4 mg/0.4 mL) eye drops, 30 x 0.4 mL unit doses</td>
<td>2324H</td>
<td>3</td>
<td>5</td>
<td>..</td>
<td>*31.63</td>
<td>32.78</td>
</tr>
<tr>
<td><strong>CARMELLOSE SODIUM</strong> 0.25% (1.5 mg/0.6 mL) eye drops, 24 x 0.6 mL unit doses</td>
<td>8823J</td>
<td>4</td>
<td>5</td>
<td>..</td>
<td>*40.76</td>
<td>37.70</td>
</tr>
<tr>
<td><strong>CARMELLOSE SODIUM</strong> 0.5% (2 mg/0.4 mL) eye drops, 30 x 0.4 mL unit doses</td>
<td>2338B</td>
<td>3</td>
<td>5</td>
<td>..</td>
<td>*34.42</td>
<td>35.57</td>
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### CARAMELLOSE SODIUM

#### Authority required

Severe dry eye syndrome in patients who are sensitive to preservatives in multi-dose eye drops

<table>
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<tr>
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<th>Max Qty Packs</th>
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<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
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<td>3</td>
<td>5</td>
<td>..</td>
<td>*31.63</td>
<td>32.78</td>
</tr>
<tr>
<td><strong>CARMELLOSE SODIUM</strong> 0.25% (1.5 mg/0.6 mL) eye drops, 24 x 0.6 mL unit doses</td>
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<td>4</td>
<td>5</td>
<td>..</td>
<td>*40.76</td>
<td>37.70</td>
</tr>
<tr>
<td><strong>CARMELLOSE SODIUM</strong> 0.5% (2 mg/0.4 mL) eye drops, 30 x 0.4 mL unit doses</td>
<td>5506T</td>
<td>3</td>
<td>5</td>
<td>..</td>
<td>*31.63</td>
<td>32.78</td>
</tr>
<tr>
<td><strong>CARMELLOSE SODIUM</strong> 1% (6 mg/0.6 mL) eye gel, 28 x 0.6 mL unit doses</td>
<td>5510B</td>
<td>3</td>
<td>5</td>
<td>..</td>
<td>*34.42</td>
<td>35.57</td>
</tr>
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</table>

### CARAMELLOSE SODIUM

#### 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.

carmellose sodium 1% (10 mg/mL) eye drops, 15 mL

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
<th>No. of Rpts</th>
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<th>DPMQ $</th>
<th>MRVSN $</th>
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</thead>
<tbody>
<tr>
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<td>10.93</td>
<td>12.08</td>
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<td>Refresh Liquigel [AG]</td>
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</tbody>
</table>

carmellose sodium 0.5% (5 mg/mL) eye drops, 15 mL

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
<th>No. of Rpts</th>
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<tbody>
<tr>
<td>‡1</td>
<td>11</td>
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<td>12.08</td>
<td></td>
<td>Refresh Tears Plus [AG]</td>
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**CARMELLOSE SODIUM + GLYCEROL**

Authority required
Severe dry eye syndrome in patients who are sensitive to preservatives in multi-dose eye drops

carmellose sodium 0.5% + glycerol 0.9% eye drops, 30 x 0.4 mL unit doses

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
<th>No. of Rpts</th>
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<tbody>
<tr>
<td>‡3</td>
<td>5</td>
<td>36.40</td>
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<td>Optive [AG]</td>
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**CARMELLOSE SODIUM + GLYCEROL**

Authority required (STREAMLINED) 1359
Severe dry eye syndrome in patients who are sensitive to preservatives in multi-dose eye drops

carmellose sodium 0.5% + glycerol 0.9% eye drops, 30 x 0.4 mL unit doses

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<tr>
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<tr>
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<td>37.55</td>
<td></td>
<td>Optive [AG]</td>
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</table>

**CARMELLOSE SODIUM + GLYCEROL**

Restricted benefit
Severe dry eye syndrome, including Sjogren’s syndrome

Note
The in-use shelf life of Optive is 6 months from the date of opening.

carmellose sodium 0.5% + glycerol 0.9% eye drops, 15 mL

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
<th>No. of Rpts</th>
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<td>10.93</td>
<td>12.08</td>
<td></td>
<td>Optive [AG]</td>
</tr>
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carmellose sodium 0.5% + glycerol 0.9% eye drops, 15 mL

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<td>10.93</td>
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<td></td>
<td>Optive [AG]</td>
</tr>
</tbody>
</table>

**CARMELLOSE SODIUM + GLYCEROL**

Restricted benefit
For use in patients who have severe dry eye syndrome, including Sjogren’s syndrome, and who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements

Note
No applications for increased maximum quantities and/or repeats will be authorised.
The in-use shelf life of Optive is 6 months from the date of opening.

carmellose sodium 0.5% + glycerol 0.9% eye drops, 15 mL

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<td>12.08</td>
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<td>Optive [AG]</td>
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</table>

**DEXTRAN-70 + HYPROMELLOSE**

Restricted benefit
Severe dry eye syndrome, including Sjogren’s syndrome

dextran-70 0.1% + hypromellose 0.3% eye drops, 15 mL

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
<th>No. of Rpts</th>
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<th>DPMQ $</th>
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<tr>
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<td>Poly-Tears [IQ]</td>
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<tr>
<td>‡2</td>
<td>2.04</td>
<td>12.87</td>
<td>11.98</td>
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<td>Tears Naturale [AQ]</td>
</tr>
</tbody>
</table>
### SENSORY ORGANS

#### dextran-0.1% + hypromellose 0.3% eye drops, 15 mL

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
</tr>
</thead>
<tbody>
<tr>
<td>Poly-Tears [IQ]</td>
<td>10.83</td>
<td>11.98</td>
<td></td>
</tr>
<tr>
<td>Tears Naturale [AQ]</td>
<td>12.87</td>
<td>11.98</td>
<td></td>
</tr>
</tbody>
</table>

**Authority required**

- Severe dry eye syndrome in patients who are sensitive to preservatives in multi-dose eye drops

#### dextran-0.1% + hypromellose 0.3% eye drops, 28 x 0.4 mL unit doses

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
</tr>
</thead>
<tbody>
<tr>
<td>Poly-Tears [IQ]</td>
<td>35.41</td>
<td>36.56</td>
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</tr>
<tr>
<td>Tears Naturale [AQ]</td>
<td>35.41</td>
<td>36.56</td>
<td></td>
</tr>
</tbody>
</table>

**Authority required**

- Severe dry eye syndrome in patients who are sensitive to preservatives in multi-dose eye drops

#### dextran-0.1% + hypromellose 0.3% eye drops, 28 x 0.4 mL unit doses

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<tbody>
<tr>
<td>Poly-Tears [IQ]</td>
<td>35.41</td>
<td>36.56</td>
<td></td>
</tr>
<tr>
<td>Tears Naturale [AQ]</td>
<td>35.41</td>
<td>36.56</td>
<td></td>
</tr>
</tbody>
</table>

**Authority required (STREAMLINED)**

- Severe dry eye syndrome in patients who are sensitive to preservatives in multi-dose eye drops

#### dextran-0.1% + hypromellose 0.3% eye drops, 15 mL

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
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</thead>
<tbody>
<tr>
<td>In a Wink Moisturising [IQ]</td>
<td>10.61</td>
<td>11.76</td>
<td></td>
</tr>
<tr>
<td>Genteal [AQ]</td>
<td>10.61</td>
<td>11.76</td>
<td></td>
</tr>
</tbody>
</table>

**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.

#### HYPROMELLOSE

- For use in patients who have severe dry eye syndrome, including Sjogren's syndrome

**Restricted benefit**

- For use in patients who have severe dry eye syndrome, including Sjogren's syndrome

#### HYPROMELLOSE Eye drops 3 mg per mL (0.3%), 15 mL (contains sodium perborate as preservative), 1

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
</tr>
</thead>
<tbody>
<tr>
<td>In a Wink Moisturising [IQ]</td>
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<td>11.76</td>
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<tr>
<td>Genteal [AQ]</td>
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<td>11.76</td>
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</tr>
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</table>

**Restricted benefit**

- For use in patients who have severe dry eye syndrome, including Sjogren's syndrome

**Note**

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### Sensory Organs

**HYPROMELLOSE Eye drops 3 mg per mL (0.3%), 15 mL (contains sodium perborate as preservative), 1**

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<tr>
<th>Max Qty</th>
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<td>11.76</td>
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<td>81.95</td>
<td>12.56</td>
<td>11.76</td>
<td>* Genteal [AQ]</td>
</tr>
</tbody>
</table>

**HYPROMELLOSE Eye drops 5 mg per mL (0.5%), 15 mL, 1**

<table>
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<tr>
<th>Max Qty</th>
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<td>Methopt [QA]</td>
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</table>

### HYPROMELLOSE + CARBOMER-980

**Restricted benefit**

Severe dry eye syndrome, including Sjogren’s syndrome

**Hypromellose 0.3% + carbomer-980 0.2% eye gel, 10 g**

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<tr>
<th>Max Qty</th>
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<tr>
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<td>10.61</td>
<td>11.76</td>
<td>* HPMC PAA [IQ]</td>
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<tr>
<td></td>
<td></td>
<td>81.95</td>
<td>12.56</td>
<td>11.76</td>
<td>* Genteal gel [AQ]</td>
</tr>
</tbody>
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**Hypromellose 0.3% + carbomer-980 0.2% eye gel, 10 g**

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<tr>
<th>Max Qty</th>
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<td>11.76</td>
<td>* HPMC PAA [IQ]</td>
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<td>81.95</td>
<td>12.56</td>
<td>11.76</td>
<td>* Genteal gel [AQ]</td>
</tr>
</tbody>
</table>

### 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 GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements

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**Hypromellose 0.3% + carbomer-980 0.2% eye gel, 10 g**

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</tbody>
</table>

### PARAFFIN

**Paraffin 1 g/g eye ointment, 2 x 3.5 g tubes**

<table>
<thead>
<tr>
<th>Max Qty</th>
<th>No. of Rpts</th>
<th>Premium $</th>
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<tbody>
<tr>
<td>‡1</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>82.12</td>
<td>23.06</td>
<td>* Ircal [PE]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Refresh Night Time [AG]</td>
</tr>
</tbody>
</table>

**Paraffin 1 g/g eye ointment, 2 x 3.5 g tubes**

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**Paraffin 1 g/g eye ointment, 3.5 g**

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<tbody>
<tr>
<td>2</td>
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<td>22.73</td>
<td>Poly Visc [IQ]</td>
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<td></td>
<td></td>
<td>82.54</td>
<td>24.12</td>
<td>22.73</td>
<td>* Duratears [AQ]</td>
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**Paraffin 1 g/g eye ointment, 3.5 g**

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<td>24.12</td>
<td>22.73</td>
<td>* Duratears [AQ]</td>
</tr>
</tbody>
</table>

### PARAFFIN

**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.
paraffin 1 g/g eye ointment, 2 x 3.5 g tubes

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>9218E</td>
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<td>20.94</td>
<td>22.09</td>
<td></td>
<td>Poly Visc [IQ]</td>
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<tr>
<td></td>
<td>9218E</td>
<td>2.12</td>
<td>23.06</td>
<td>22.09</td>
<td>* Refresh Night Time [AG]</td>
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</table>

paraffin 1 g/g eye ointment, 3.5 g

<table>
<thead>
<tr>
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<tr>
<td></td>
<td>9217D</td>
<td>2.54</td>
<td>24.12</td>
<td>22.73</td>
<td>* Duratears [AQ]</td>
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</tbody>
</table>

**PARAFFIN**

Note

The in-use shelf life of VitA-POS is 6 months from the date of opening.

paraffin + retinyl palmitate 138 microgram/g (equivalent to 250 units/g vitamin A) eye ointment, 5 g

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
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paraffin + retinyl palmitate 138 microgram/g (equivalent to 250 units/g vitamin A) eye ointment, 5 g

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<thead>
<tr>
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<td>22.73</td>
<td></td>
<td>VitA-POS [AE]</td>
</tr>
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</table>

**PARAFFIN**

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

The in-use shelf life of VitA-POS is 6 months from the date of opening.

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

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

paraffin + retinyl palmitate 138 microgram/g (equivalent to 250 units/g vitamin A) eye ointment, 5 g

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<tr>
<td>2202X</td>
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<td>21.58</td>
<td>22.73</td>
<td></td>
<td>VitA-POS [AE]</td>
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</table>

**POLYETHYLENE GLYCOL-400 + PROPYLENE GLYCOL**

Restricted benefit

Severe dry eye syndrome, including Sjogren’s syndrome

polyethylene glycol-400 0.4% + propylene glycol 0.3% eye drops, 15 mL

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
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<th>MRVSN $</th>
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<td>Systane [AQ]</td>
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</tbody>
</table>

polyethylene glycol-400 0.4% + propylene glycol 0.3% eye drops, 15 mL

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
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<td>12.08</td>
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<td>Systane [AQ]</td>
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</tbody>
</table>

**POLYETHYLENE GLYCOL-400 + PROPYLENE GLYCOL**

Authority required

Severe dry eye syndrome in patients who are sensitive to preservatives in multi-dose eye drops

polyethylene glycol-400 0.4% + propylene glycol 0.3% eye drops, 28 x 0.8 mL unit doses

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
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<tr>
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<td>35.57</td>
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<td>Systane [AQ]</td>
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</table>

**POLYETHYLENE GLYCOL-400 + PROPYLENE GLYCOL**

Authority required (STREAMLINED)

1359

Severe dry eye syndrome in patients who are sensitive to preservatives in multi-dose eye drops

polyethylene glycol-400 0.4% + propylene glycol 0.3% eye drops, 28 x 0.8 mL unit doses

<table>
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<tr>
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<th>No. of Rpts</th>
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</table>
POLYETHYLENE GLYCOL-400 + PROPYLENE GLYCOL

Restricted benefit
For use in patients who have severe dry eye syndrome, including Sjogren’s syndrome, and who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements

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

polyethylene glycol-400 0.4% + propylene glycol 0.3% eye drops, 15 mL
9219F

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
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<tr>
<td>‡1</td>
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<td>10.93</td>
<td>12.08</td>
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<td>Systane [AQ]</td>
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</tbody>
</table>

POLYVINYL ALCOHOL

Restricted benefit
Severe dry eye syndrome, including Sjogren’s syndrome

polyvinyl alcohol 1.4% eye drops, 15 mL
2682E

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
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<tbody>
<tr>
<td>‡1</td>
<td>5</td>
<td>10.61</td>
<td>11.76</td>
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<td>* PVA Tears [PE]</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1.60</td>
<td>12.21</td>
<td></td>
<td>* Liquifilm Tears [AG]</td>
</tr>
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</table>

polyvinyl alcohol 1.4% eye drops, 15 mL
5526W

<table>
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<tr>
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<td>1.60</td>
<td>12.21</td>
<td></td>
<td>* Liquifilm Tears [AG]</td>
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polyvinyl alcohol 1.4% eye drops, 15 mL
5527X

<table>
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<tr>
<td>‡1</td>
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<td>Vistil [AE]</td>
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</table>

polyvinyl alcohol 1.4% eye drops, 15 mL
8831T

<table>
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<tr>
<td>‡1</td>
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polyvinyl alcohol 3% eye drops, 15 mL
5528Y

<table>
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<tr>
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<td>11.76</td>
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<td>Vistil Forte [AE]</td>
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</table>

polyvinyl alcohol 3% eye drops, 15 mL
8832W

<table>
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<tr>
<th>Max Qty Packs</th>
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<td>10.61</td>
<td>11.76</td>
<td></td>
<td>Vistil Forte [AE]</td>
</tr>
</tbody>
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POLYVINYL ALCOHOL

Restricted benefit
For use in patients who have severe dry eye syndrome, including Sjogren’s syndrome, and who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements

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

polyvinyl alcohol 1.4% eye drops, 15 mL
9220G

<table>
<thead>
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<tr>
<td></td>
<td></td>
<td>1.60</td>
<td>12.21</td>
<td></td>
<td>* Liquifilm Tears [AG]</td>
</tr>
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</table>

polyvinyl alcohol 1.4% eye drops, 15 mL
9221H

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
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<td>10.61</td>
<td>11.76</td>
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<td>Vistil [AE]</td>
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polyvinyl alcohol 3% eye drops, 15 mL
9223K

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<td>11.76</td>
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<td>Vistil Forte [AE]</td>
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</tbody>
</table>

SODIUM HYALURONATE

Authority required
Severe dry eye syndrome
SENSORY ORGANS

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.

sodium hyaluronate 0.1% (1 mg/mL) eye drops, 10 mL

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
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<td>t1</td>
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<td>33.96</td>
<td>35.11</td>
<td>Hylo-Fresh [AE]</td>
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</tbody>
</table>

sodium hyaluronate 0.2% (2 mg/mL) eye drops, 10 mL

<table>
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<tr>
<th>Max Qty Packs</th>
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<td>35.11</td>
<td>Hylo-Forte [AE]</td>
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**SODIUM HYALURONATE**

**Authority required (STREAMLINED)**

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.

sodium hyaluronate 0.1% (1 mg/mL) eye drops, 10 mL

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<td>35.11</td>
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sodium hyaluronate 0.2% (2 mg/mL) eye drops, 10 mL

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<td>33.96</td>
<td>35.11</td>
<td>Hylo-Forte [AE]</td>
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</tbody>
</table>

**SOY LECITHIN + TOCOPHEROLS + VITAMIN A**

**Authority required**

Severe dry eye syndrome in patients who are sensitive to preservatives in multi-dose eye drops

soy lecithin 1% (10 mg/mL) + tocopherols 0.002% (20 microgram/mL) + vitamin A palmitate 0.025% (250 microgram/mL) eye spray, 100 actuations

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
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<tbody>
<tr>
<td>2</td>
<td>5</td>
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<td>*36.40</td>
<td>37.55</td>
<td>tearsagain [RB]</td>
</tr>
</tbody>
</table>

**SOY LECITHIN + TOCOPHEROLS + VITAMIN A**

**Authority required (STREAMLINED)**

Severe dry eye syndrome in patients who are sensitive to preservatives in multi-dose eye drops

soy lecithin 1% (10 mg/mL) + tocopherols 0.002% (20 microgram/mL) + vitamin A palmitate 0.025% (250 microgram/mL) eye spray, 100 actuations

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<td>..</td>
<td>*36.40</td>
<td>37.55</td>
<td>tearsagain [RB]</td>
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</tbody>
</table>

**OTOLOGICALS**

**ANTIINFECTIVES**

**Antiinfectives**

**CIPROFLOXACIN**

**Authority required**

Treatment of chronic suppurative otitis media in an Aboriginal or a Torres Strait Islander person aged 1 month or older

**Authority required**

Treatment of chronic suppurative otitis media in a patient less than 18 years of age with perforation of the tympanic membrane

**Authority required**

Treatment of chronic suppurative otitis media in a patient less than 18 years of age with a grommet in situ

ciprofloxacin 0.3% ear drops, 5 mL

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
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<tbody>
<tr>
<td>t1</td>
<td>1</td>
<td>..</td>
<td>19.62</td>
<td>20.77</td>
<td>Ciloxan [AQ]</td>
</tr>
</tbody>
</table>
**Corticosteroids and antiinfectives in combination**

- **DEXAMETHASONE + FRAMYCETIN SULFATE + GRAMICIDIN**
  - dexamethasone 0.05% (500 microgram/mL) + framycetin sulfate 0.5% (5 mg/mL) + gramicidin 0.005% (50 microgram/mL) ear drops, 8 mL
  - Max Qty Packs | No. of Rpts | Premium | DPMQ | MRVSN | Brand Name and Manufacturer
  - ‡1 | 2 | .. | 10.28 | 11.43 | * Otodex [AV]
  - §1.91 | 1.19 | 12.19 | 11.43 | * Sofradex [SW]

- **TRIAMCINOLONE + NEOMYCIN SULFATE + GRAMICIDIN + NYSTATIN**
  - triamcinolone acetonide 0.1% + neomycin sulfate 0.25% + gramicidin 0.025% + nystatin 100 000 international units/g ointment, 5 g
  - Max Qty Packs | No. of Rpts | Premium | DPMQ | MRVSN | Brand Name and Manufacturer
  - ‡1 | 2 | .. | 8.52 | 9.67 | * Otocomb Otic [FM]
  - §1.95 | 1.19 | 10.47 | 9.67 | * Kenacomb Otic [QA]

- **OPHTHALMOLOGICAL AND OTOLOGICAL PREPARATIONS**
  - **ANTIINFECTIVES**
    - **FRAMYCETIN SULFATE**
      - framycetin sulfate 0.5% (5 mg/mL) eye/ear drops, 8 mL
      - Max Qty Packs | No. of Rpts | Premium | DPMQ | MRVSN | Brand Name and Manufacturer
      - ‡1 | 2 | .. | 11.08 | 12.23 | Soframycin [SW]

- **ALLERGENS**
  - **BEE VENOM**
    - bee venom 550 microgram injection [1 x 550 microgram vial] (&) inert substance diluent [4 vials], 1 pack
    - Max Qty Packs | No. of Rpts | Premium | DPMQ | MRVSN | Brand Name and Manufacturer
    - 1 | .. | .. | 238.72 | 37.70 | Albey Bee Venom [HL]

**PAPER WASP VENOM**

Note

Paper wasp venom is not European wasp venom.

- paper wasp venom 550 microgram injection [1 x 550 microgram vial] (&) inert substance diluent [4 vials], 1 pack
  - Max Qty Packs | No. of Rpts | Premium | DPMQ | MRVSN | Brand Name and Manufacturer
  - 1 | .. | .. | 238.72 | 37.70 | Albey Paper Wasp Venom [HL]

- **VESPIDA SPP VENOM**
  - vespidula spp venom 550 microgram injection [1 x 550 microgram vial] (&) inert substance diluent [4 vials], 1 pack
  - Max Qty Packs | No. of Rpts | Premium | DPMQ | MRVSN | Brand Name and Manufacturer
  - 1 | .. | .. | 238.72 | 37.70 | Albey Yellow Jacket Venom [HL]
ALL OTHER THERAPEUTIC PRODUCTS

Antidotes

NALOXONE

naloxone hydrochloride 400 microgram/mL injection, 1 x 1 mL syringe

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
<th>No. of Rpts</th>
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<tbody>
<tr>
<td>5</td>
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<td>..</td>
<td>*105.16</td>
<td>37.70</td>
<td>Naloxone minijet [UC]</td>
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naloxone hydrochloride 400 microgram/mL injection, 1 x 1 mL syringe

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
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<td>*105.16</td>
<td>37.70</td>
<td>Naloxone minijet [UC]</td>
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Drugs for treatment of hyperkalemia and hyperphosphatemia

LANTHANUM

Authority required (STREAMLINED)

Hyperphosphataemia

Treatment Phase: Maintenance following initiation and stabilisation

Clinical criteria:
The condition must not be adequately controlled by calcium, AND
Patient must have a serum phosphate of greater than 1.6 mmol per L at the commencement of therapy; OR
The condition must be where a serum calcium times phosphate product is greater than 4 at the commencement of therapy, AND
The treatment must not be used in combination with any other phosphate binding agents.

Treatment criteria:
Patient must be undergoing dialysis for chronic kidney disease.

Note

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

LANTHANUM Tablet, chewable, 1000 mg (as carbonate hydrate), 90

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LANTHANUM Tablet, chewable, 500 mg (as carbonate hydrate), 90

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LANTHANUM Tablet, chewable, 750 mg (as carbonate hydrate), 90

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SEVELAMER

Authority required (STREAMLINED)

Hyperphosphataemia

Treatment Phase: Maintenance following initiation and stabilisation

Clinical criteria:
The condition must not be adequately controlled by calcium, AND
Patient must have a serum phosphate of greater than 1.6 mmol per L at the commencement of therapy; OR
The condition must be where a serum calcium times phosphate product is greater than 4 at the commencement of therapy, AND
The treatment must not be used in combination with any other phosphate binding agents.

Treatment criteria:
Patient must be undergoing dialysis for chronic kidney disease.

Note

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

**Authority required (STREAMLINED)**

**4827**

Hyperphosphataemia

**Treatment Phase:** Maintenance following initiation and stabilisation

**Clinical criteria:**

- The condition must not be adequately controlled by calcium, AND
- Patient must have a serum phosphate of greater than 1.6 mmol per L at the commencement of therapy; OR
- The condition must be where a serum calcium times phosphate product is greater than 4 at the commencement of therapy, AND
- The treatment must not be used in combination with any other phosphate binding agents.

**Treatment criteria:**

- Patient must be undergoing dialysis for chronic kidney disease.

**Note**

**Shared Care Model:**

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

---

### Detoxifying agents for antineoplastic treatment

### FOLINIC ACID

#### folinic acid 1 g/100 mL injection, 1 x 100 mL vial

**8969C**

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#### folinic acid 300 mg/30 mL injection, 1 x 30 mL vial

**9041W**

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* Leucovorin Calcium (Hospira Pty Limited) [HH]

---

### FOLINIC ACID

**Note**

For item codes 8740B and 1610R, pharmaceutical benefits that have the form injection equivalent to 50 mg folinic acid in 5 mL are equivalent for the purposes of substitution.

#### folinic acid 50 mg/5 mL injection, 1 x 5 mL vial

**8740B**

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#### folinic acid 50 mg/5 mL injection, 10 x 5 mL ampoules

**1610R**

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<td>* Leucovorin Calcium (Pfizer Australia Pty Ltd) [PF]</td>
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### 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.

#### folinic acid 100 mg/10 mL injection, 1 x 10 mL vial

**8812T**

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folic acid 100 mg/10 mL injection, 10 x 10 mL ampoules
1704Q

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**FOLINIC ACID**

*Restricted benefit*

Antidote to folic acid antagonists

folic acid 15 mg tablet, 10
2308L

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**MESNA**

*Restricted benefit*

Adjunctive therapy for use with ifosfamide or high dose cyclophosphamide

mesna 1 g/10 mL injection, 15 x 10 mL ampoules
8079F

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mesna 400 mg/4 mL injection, 15 x 4 mL ampoules
8078E

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**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

phosphorus 500 mg tablet: effervescent, 100
2946C

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**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).

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

polylactic acid 150 mg injection, 1 x 150 mg vial
9475Q

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<td>*446.80</td>
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<td>Sculptra [GA]</td>
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**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). 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.

poly-l-lactic acid 150 mg injection, 1 x 150 mg vial

9476R

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<td>*446.80</td>
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\section*{GLUCOSE AND KETONE INDICATOR URINE}

\subsection*{URINE TESTS}

\subsection*{GLUCOSE AND KETONE INDICATOR URINE}

glucose and ketone indicator urine strip: diagnostic, 50 diagnostic strips

3106L

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</thead>
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<td>*17.64</td>
<td>18.79</td>
<td>Keto-Diabur: Test 5000 [RD]</td>
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\subsection*{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.

glucose and ketone indicator urine strip: diagnostic, 50 diagnostic strips

9254C

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\subsection*{GLUCOSE INDICATOR URINE}

glucose indicator urine strip: diagnostic, 50 diagnostic strips

3104J

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\subsection*{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.

glucose indicator urine strip: diagnostic, 50 diagnostic strips

9255D

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\subsection*{GLUCOSE INDICATOR BLOOD}

glucose indicator blood strip: diagnostic, 100

10101P

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**glucose indicator blood strip: diagnostic, 50**

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<tbody>
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<tr>
<td>2673Q</td>
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<td>2860M</td>
<td>Betachek G5 [NA]</td>
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<td>2890D</td>
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<td>Accu-Chek Aviva [RD]</td>
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<tr>
<td>3406G</td>
<td>CareSens N [PB]</td>
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<tr>
<td>3441D</td>
<td>OneTouch Verio [JJ]</td>
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<td>5043K</td>
<td>PanOpti-Pen [PB]</td>
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<tr>
<td>8739Y</td>
<td>Accu-Chek Go [RD]</td>
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<td>8749L</td>
<td>Lifeline Attest [OI]</td>
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<td>9298J</td>
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<tr>
<td>9471L</td>
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**glucose indicator blood strip: diagnostic, 51 diagnostic strips**

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<tbody>
<tr>
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GLUCOSE INDICATOR BLOOD
Restricted benefit
For use in patients on insulin therapy

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>Accu-Chek Mobile [RD]</td>
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GLUCOSE INDICATOR BLOOD
Restricted benefit
For use in patients on insulin therapy who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements

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

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>Accu-Chek Mobile [RD]</td>
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</table>

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

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
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<tr>
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GLUCOSE INDICATOR BLOOD
Restricted benefit

<table>
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GLUCOSE INDICATOR BLOOD
Restricted benefit

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GLUCOSE INDICATOR BLOOD
Restricted benefit

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GLUCOSE INDICATOR BLOOD
Restricted benefit

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GLUCOSE INDICATOR BLOOD
Restricted benefit

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General

GLUCOSE INDICATOR BLOOD
Restricted benefit
For use in patients on insulin therapy
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<td>Accu-Chek Go [RD]</td>
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</table>
## 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 long chain oral liquid, 18 x 250 mL cartons**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
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<td>11</td>
<td>..</td>
<td>*53.52</td>
<td>37.70</td>
<td>Carbzero [VF]</td>
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#### TRIGLYCERIDES MEDIUM CHAIN

**Authority required**

Ketogenic diet

**Clinical criteria:**

- Patient must have intractable seizures requiring treatment with a ketogenic diet; OR
- Patient must have a glucose transport protein defect; OR
- Patient must have pyruvate dehydrogenase deficiency.

**Authority required**

Dietary management of conditions requiring a source of medium chain triglycerides

**Clinical criteria:**
Patient must have chylous 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.
No increase in the maximum number of repeats may be authorised.

### triglycerides medium chain oral liquid, 18 x 250 mL cartons

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
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### 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 oil: oral, 500 mL

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<th>Max Qty Packs</th>
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<tbody>
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</table>

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

### triglycerides medium chain oral liquid, 1 x 250 mL bottle

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<th>No. of Rpts</th>
<th>Premium $</th>
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<td>214.76</td>
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**Note**
No applications for increased maximum quantities and/or repeats will be authorised.

### 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.

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<th>1521C</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMO $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<td></td>
<td>12</td>
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<td>*532.00</td>
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<table>
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<th>Brand Name and Manufacturer</th>
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<td>*532.00</td>
<td>37.70</td>
<td>EleCare [AB]</td>
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</table>

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

### Amino Acid Synthetic Formula Oral Liquid: Powder for, 400 g

<table>
<thead>
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<th>Max Qty Pacs</th>
<th>No. of Rpts</th>
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<tbody>
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<tr>
<td>Neocate Advance [SB]</td>
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<td>5</td>
<td>*361.48</td>
<td>37.70</td>
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</table>

### 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.

### amino acid synthetic formula oral liquid: powder for, 400 g

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### amino acid synthetic formula oral liquid: powder for, 400 g

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### amino acid synthetic formula oral liquid: powder for, 400 g

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- **AMINO ACID SYNTHETIC FORMULA SUPPLEMENTED WITH LONG CHAIN POLYUNSATURATED FATTY ACIDS**

**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 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

**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

**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.
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**

  **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.

| amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids oral liquid: powder for, 400 g |
|---|---|---|---|---|---|
| Max Qty Packs | No of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer |
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| 9340N | 8 | 5 | ... | *368.20 | 37.70 | EleCare LCP [AB] |

**AMINO ACID SYNTHETIC FORMULA SUPPLEMENTED WITH LONG CHAIN POLYUNSATURATED FATTY ACIDS AND MEDIUM CHAIN TRIGLYCERIDES**

**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.

amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids and medium chain triglycerides oral liquid: powder for, 400 g

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AMINO ACID SYNTHETIC FORMULA SUPPLEMENTED WITH LONG CHAIN POLYUNSATURATED FATTY ACIDS AND MEDIUM CHAIN TRIGLYCERIDES

Authority required
Cows' milk protein enteropathy
Treatment Phase: Continuing treatment

Clinical criteria:
The condition must not be isolated infant colic or reflux, AND Patient must be intolerant to both soy protein and protein hydrolysate formulae, as demonstrated when the child has failed to respond to a strict cows' milk protein free and strict soy protein free diet with a protein hydrolysate (with or without medium chain triglycerides) as the principal formula.

Population criteria:
Patient must be up to the age of 24 months.

Treatment criteria:
Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or have an appointment to be assessed by one of these specialists.
The name of the specialist and the date of birth of the patient must be included in the authority application.

Authority required
Severe cows' milk protein enteropathy with failure to thrive
Treatment Phase: Continuing treatment

Clinical criteria:
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:
General

Patient must have failed a trial of protein hydrolysate formulae (with or without medium chain triglycerides) prior to commencement with initial treatment.

**Population criteria:**
Patient must be up to the age of 24 months.

**Treatment criteria:**
Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.
The name of the specialist and the date of birth of the patient must be included in the authority application.

**Note**
Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.

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**AMINO ACID SYNTHETIC FORMULA SUPPLEMENTED WITH LONG CHAIN POLYUNSATURATED FATTY ACIDS AND MEDIUM CHAIN TRIGLYCERIDES**

**Authority required**
Cows’ milk protein enteropathy
Treatment Phase: Initial treatment for up to 6 months

**Clinical criteria:**
The condition must not be isolated infant colic or reflux, AND
Patient must be intolerant to both soy protein and protein hydrolysate formulae, as demonstrated when the child has failed to respond to a strict cows’ milk protein free and strict soy protein free diet with a protein hydrolysate (with or without medium chain triglycerides) as the principal formula.

**Population criteria:**
Patient must be up to the age of 24 months.

**Treatment criteria:**
Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.
The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**
Severe cows’ milk protein enteropathy with failure to thrive
Treatment Phase: Initial treatment for up to 6 months

**Clinical criteria:**
The condition must not be isolated infant colic or reflux.

**Population criteria:**
Patient must be up to the age of 24 months.

**Treatment criteria:**
Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.
The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**
Combined intolerance to cows’ milk protein, soy protein and protein hydrolysate formulae
Treatment Phase: Initial treatment for up to 6 months

**Clinical criteria:**
The condition must not be isolated infant colic or reflux.

**Population criteria:**
Patient must be older than 24 months of age.

**Treatment criteria:**
Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.
The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**
Proven combined immunoglobulin E (IgE) mediated allergy to cows’ milk protein and soy protein
Treatment Phase: Initial treatment for up to 6 months

**Clinical criteria:**
Patient must have failed a trial of protein hydrolysate formulae (with or without medium chain triglycerides).

**Population criteria:**
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.
No increase in the maximum number of repeats may be authorised.

**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**

**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 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**

**Combined intolerance to cows’ milk protein, soy protein and protein hydrolysate formulae**

**Treatment Phase: Continuing treatment**

**Clinical criteria:**
The condition must not be isolated infant colic or reflux.

**Population criteria:**
Patient must be older than 24 months of age.

**Treatment criteria:**
Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist at intervals not greater than 12 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

**Proven combined immunoglobulin E (IgE) mediated allergy to cows’ milk protein and soy protein**

**Treatment Phase: Continuing treatment**

**Clinical criteria:**
Patient must have failed a trial of protein hydrolysate formulae (with or without medium chain triglycerides) prior to commencement with initial treatment.
**Population criteria:**
Patient must be up to the age of 24 months.

**Treatment criteria:**
Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist. The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**
Severe intestinal malabsorption including short bowel syndrome

**Clinical criteria:**
Patient must have failed to respond to protein hydrolysate formulae; OR
Patient must have been receiving parenteral nutrition.

**Note**
Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.

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**PROTEIN HYDROLYSATE FORMULA WITH MEDIUM CHAIN TRIGLYCERIDES**

**Authority required**
Cows' milk protein enteropathy and intolerance to soy protein

**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

**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.

### PROTEIN HYDROLYSATE FORMULA WITH MEDIUM CHAIN TRIGLYCERIDES

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**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 paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist, 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 paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist, 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.
No increase in the maximum number of repeats may be authorised.

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**protein hydrolysate formula with medium chain triglycerides oral liquid: powder for, 400 g**

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**TRIGLYCERIDES MEDIUM CHAIN FORMULA**

**Restricted benefit**
Dietary management of conditions requiring a source of medium chain triglycerides

**Clinical criteria:**
Patient must have fat malabsorption due to liver disease; OR Patient must have fat malabsorption due to short gut syndrome; OR Patient must have fat malabsorption due to cystic fibrosis; OR Patient must have fat malabsorption due to gastrointestinal disorders.

**Note**
No increase in the maximum number of repeats may be authorised.
No increase in the maximum quantity or number of units may be authorised.
Not indicated for the treatment of intractable childhood epilepsy or cerebrospinal fluid glucose transporter defect requiring a ketogenic diet.

- **TRIGLYCERIDES MEDIUM CHAIN FORMULA**
  - Restricted benefit
  - Hyperlipoproteinaemia type 1
  - Restricted benefit
  - Long chain fatty acid oxidation disorders
  - Restricted benefit
  - Chylous ascites
  - Restricted benefit
  - Chylothorax

  **Note**
  - No increase in the maximum number of repeats may be authorised.
  - No increase in the maximum quantity or number of units may be authorised.
  - Not indicated for the treatment of intractable childhood epilepsy or cerebrospinal fluid glucose transporter defect requiring a ketogenic diet.

- **AMYLOPECTIN MODIFIED LONG CHAIN**
  - Restricted benefit
  - Glycogen storage disease

- **MILK SUBSTITUTE**
  - **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.

- **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:
General

(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.

milk powder lactose free formula oral liquid: powder for, 900 g

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**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.

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.

milk powder lactose free formula predigested oral liquid: powder for, 900 g

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>2989H</td>
<td>5</td>
<td>5</td>
<td>..</td>
<td>*95.76</td>
<td>Karicare Aptamil Gold De-Lact [NU]</td>
</tr>
</tbody>
</table>

**MILK POWDER LACTOSE FREE FORMULA PREDIGESTED**

Authority required
Acute lactose intolerance

Population criteria:
Patient must be up to the age of 12 months.
The date of birth of the patient must be included in the authority application.

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.
No more than 1 application per patient will be authorised.

milk powder lactose free formula predigested oral liquid: powder for, 900 g

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>2975N</td>
<td>5</td>
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<td>..</td>
<td>95.76</td>
<td>Karicare Aptamil Gold De-Lact [NU]</td>
</tr>
</tbody>
</table>

**MILK POWDER LACTOSE MODIFIED PREDIGESTED**

Authority required
Proven chronic lactose intolerance in children aged 1 year and over who are significantly malnourished. 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.

milk powder lactose modified predigested oral liquid: powder for, 900 g

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>2357C</td>
<td>3</td>
<td>10</td>
<td>..</td>
<td>73.15</td>
<td>Digestelact [SJ]</td>
</tr>
</tbody>
</table>
**MILK POWDER LACTOSE MODIFIED PREDIGESTED**

**Authority required**
Acute lactose intolerance in children aged 1 year and over. 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>milk powder lactose modified predigested oral liquid: powder for, 900 g</th>
</tr>
</thead>
<tbody>
<tr>
<td>Max Qty Packs</td>
</tr>
<tr>
<td>2358D</td>
</tr>
</tbody>
</table>

**MILK POWDER SYNTHETIC LOW CALCIUM**

**Authority required**
Hypercalcaemia in children under the age of 4 years.

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

<table>
<thead>
<tr>
<th>milk powder synthetic low calcium oral liquid: powder for, 400 g</th>
</tr>
</thead>
<tbody>
<tr>
<td>Max Qty Packs</td>
</tr>
<tr>
<td>3092R</td>
</tr>
</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>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</th>
</tr>
</thead>
<tbody>
<tr>
<td>Max Qty Packs</td>
</tr>
<tr>
<td>3417W</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>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</th>
</tr>
</thead>
<tbody>
<tr>
<td>Max Qty Packs</td>
</tr>
<tr>
<td>9330C</td>
</tr>
</tbody>
</table>

**AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT LYSINE AND LOW IN TRYPТОPHAN**

**Restricted benefit**
A patient aged 3 years or older with proven glutaric aciduria type 1.

<table>
<thead>
<tr>
<th>amino acid formula with vitamins and minerals without lysine and low in tryptophan oral liquid: powder for, 30 x 25 g sachets</th>
</tr>
</thead>
<tbody>
<tr>
<td>Max Qty Packs</td>
</tr>
<tr>
<td>5484P</td>
</tr>
</tbody>
</table>

**AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT LYSINE AND LOW IN TRYPТОPHAN**

**Restricted benefit**
A child aged from 6 months up to 10 years with proven glutaric aciduria type 1.

<table>
<thead>
<tr>
<th>amino acid formula with vitamins and minerals without lysine and low in tryptophan oral liquid: powder for, 30 x 24 g sachets</th>
</tr>
</thead>
<tbody>
<tr>
<td>Max Qty Packs</td>
</tr>
<tr>
<td>9438R</td>
</tr>
</tbody>
</table>
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 lysine and low in tryptophan oral liquid: powder for, 500 g

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>2646G</td>
<td>8</td>
<td>5</td>
<td></td>
<td>*1785.08</td>
<td>XLYS, LOW TRY Maxamaid [SB]</td>
</tr>
</tbody>
</table>

AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT LYSINE AND LOW IN TRYPTOPHAN

Restricted benefit
An infant or young child with proven glutaric aciduria type 1

amino acid formula with vitamins and minerals without lysine and low in tryptophan oral liquid: powder for, 400 g

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>2650L</td>
<td>8</td>
<td>5</td>
<td></td>
<td>*769.64</td>
<td>GA1 Anamix infant [SB]</td>
</tr>
</tbody>
</table>

AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT METHIONINE

Restricted benefit
Pyridoxine non-responsive homocystinuria

AMINO ACID FORMULA with VITAMINS and MINERALS without METHIONINE Oral liquid 125 mL, 30, 1

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>1548L</td>
<td>3</td>
<td>5</td>
<td></td>
<td>*3098.68</td>
<td>HCU Lophlex LQ 20 [SB]</td>
</tr>
</tbody>
</table>

AMINO ACID FORMULA with vitamins and minerals without methionine oral liquid, 30 x 130 mL cans

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>9133Q</td>
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<td>5</td>
<td></td>
<td>*3098.72</td>
<td>HCU cooler 15 [VF]</td>
</tr>
</tbody>
</table>

AMINO ACID FORMULA with vitamins and minerals without methionine oral liquid, 30 x 174 mL sachets

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>2640Y</td>
<td>4</td>
<td>5</td>
<td></td>
<td>*3098.72</td>
<td>HCU cooler 20 [VF]</td>
</tr>
</tbody>
</table>

AMINO ACID FORMULA with vitamins and minerals without methionine oral liquid, 30 x 87 mL sachets

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>2639X</td>
<td>4</td>
<td>5</td>
<td></td>
<td>*2114.72</td>
<td>HCU cooler 10 [VF]</td>
</tr>
</tbody>
</table>

AMINO ACID FORMULA with vitamins and minerals without methionine oral liquid: powder for, 30 x 24 g sachets

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>8677Q</td>
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<td>5</td>
<td></td>
<td>*2114.72</td>
<td>HCU gel [VF]</td>
</tr>
</tbody>
</table>

AMINO ACID FORMULA with vitamins and minerals without methionine oral liquid: powder for, 30 x 25 g sachets

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>8744F</td>
<td>4</td>
<td>5</td>
<td></td>
<td>*2114.72</td>
<td>HCU express 15 [VF]</td>
</tr>
</tbody>
</table>

AMINO ACID FORMULA with vitamins and minerals without methionine oral liquid: powder for, 500 g

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>8328H</td>
<td>8</td>
<td>5</td>
<td></td>
<td>*1785.08</td>
<td>XMET Maxamaid [SB]</td>
</tr>
</tbody>
</table>

AMINO ACID FORMULA with vitamins and minerals without methionine oral liquid: powder for, 400 g

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>8416Y</td>
<td>8</td>
<td>5</td>
<td></td>
<td>*2705.08</td>
<td>XMET Maxamum [SB]</td>
</tr>
</tbody>
</table>

AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT METHIONINE

Restricted benefit
For infants and very young children with pyridoxine non-responsive homocystinuria

amino acid formula with vitamins and minerals without methionine oral liquid: powder for, 400 g

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>8417B</td>
<td>8</td>
<td>5</td>
<td></td>
<td>*769.64</td>
<td>HCU Anamix infant [SB]</td>
</tr>
</tbody>
</table>
### AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT METHIONINE, THREONINE AND VALINE AND LOW IN ISOLEUCINE

**Restricted benefit**
Methylmalonic acidemia

**Restricted benefit**
Propionic acidemia

**AMINO ACID FORMULA with VITAMINS and MINERALS without METHIONINE, THREONINE and VALINE and low in ISOLEUCINE Oral liquid 130 mL, 30, 1**

<table>
<thead>
<tr>
<th>Schedule</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1923F</td>
<td>Max Qty Packs</td>
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<td>5</td>
<td>..</td>
<td>*3098.72</td>
<td>37.70 MMA/PA cooler 15 [VF]</td>
</tr>
<tr>
<td></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></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3444G</td>
<td>Max Qty Packs</td>
<td>4</td>
<td>5</td>
<td>..</td>
<td>*2114.72</td>
<td>37.70 MMA/PA gel [VF]</td>
</tr>
<tr>
<td></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></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>3443F</td>
<td>Max Qty Packs</td>
<td>4</td>
<td>5</td>
<td>..</td>
<td>*3098.72</td>
<td>37.70 MMA/PA express 15 [VF]</td>
</tr>
<tr>
<td></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></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>8058D</td>
<td>Max Qty Packs</td>
<td>8</td>
<td>5</td>
<td>..</td>
<td>*769.64</td>
<td>37.70 MMA/PA Anamix infant [SB]</td>
</tr>
<tr>
<td></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>
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<td></td>
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<td></td>
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<tr>
<td>8059E</td>
<td>Max Qty Packs</td>
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<td>5</td>
<td>..</td>
<td>*1785.08</td>
<td>37.70 XMTVI Maxamaid [SB]</td>
</tr>
<tr>
<td></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>
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<td>8061G</td>
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<td>5</td>
<td>..</td>
<td>*2705.08</td>
<td>37.70 XMTVI Maxamum [SB]</td>
</tr>
</tbody>
</table>

### AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT PHENYLALANINE

**Restricted benefit**
Phenylketonuria

**AMINO ACID FORMULA with VITAMINS and MINERALS without PHENYLALANINE Sachets 18.2 g, 60, 1**

<table>
<thead>
<tr>
<th>Schedule</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>1411G</td>
<td>Max Qty Packs</td>
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<td>5</td>
<td>..</td>
<td>*1640.41</td>
<td>37.70 add-ins [SB]</td>
</tr>
<tr>
<td>AMINO ACID FORMULA with VITAMINS and MINERALS without PHENYLALANINE Sachets 34 g, 30, 1</td>
<td></td>
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<td></td>
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<tr>
<td>1909L</td>
<td>Max Qty Packs</td>
<td>4</td>
<td>5</td>
<td>..</td>
<td>*2054.36</td>
<td>37.70 PKU express 20 [VF]</td>
</tr>
<tr>
<td>AMINO ACID FORMULA with VITAMINS and MINERALS without PHENYLALANINE oral liquid, 18 x 250 mL cans</td>
<td></td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>8746H</td>
<td>Max Qty Packs</td>
<td>5</td>
<td>5</td>
<td>..</td>
<td>*1313.61</td>
<td>37.70 Easiphen [SB]</td>
</tr>
<tr>
<td>AMINO ACID FORMULA with VITAMINS and MINERALS without PHENYLALANINE oral liquid, 30 x 125 mL cans</td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>9021T</td>
<td>Max Qty Packs</td>
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<td>5</td>
<td>..</td>
<td>*1549.78</td>
<td>37.70 PKU Lophlex LQ 20 [SB]</td>
</tr>
<tr>
<td>AMINO ACID FORMULA with VITAMINS and MINERALS without PHENYLALANINE oral liquid, 30 x 130 mL cans</td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>8846N</td>
<td>Max Qty Packs</td>
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<td>5</td>
<td>..</td>
<td>*1548.68</td>
<td>37.70 PKU Cooler 15 [VF]</td>
</tr>
<tr>
<td>AMINO ACID FORMULA with VITAMINS and MINERALS without PHENYLALANINE oral liquid, 30 x 174 mL cans</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2474F</td>
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<td>5</td>
<td>..</td>
<td>*2054.36</td>
<td>37.70 PKU Cooler 20 [VF]</td>
</tr>
<tr>
<td>Item Code</td>
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<td>No. of Rpts</td>
<td>Premium $</td>
<td>DPMO $</td>
<td>MRVSN $</td>
<td>Brand Name and Manufacturer</td>
</tr>
<tr>
<td>-----------</td>
<td>--------------</td>
<td>-------------</td>
<td>-----------</td>
<td>---------</td>
<td>----------</td>
<td>-----------------------------</td>
</tr>
<tr>
<td>5483N</td>
<td>4</td>
<td>5</td>
<td>..</td>
<td>1058.96</td>
<td>37.70</td>
<td>PKU squeeze [VF]</td>
</tr>
<tr>
<td>2382J</td>
<td>4</td>
<td>5</td>
<td>..</td>
<td>1035.12</td>
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<tr>
<td>9396M</td>
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<td>5</td>
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<td>1270.20</td>
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<tr>
<td>9397N</td>
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<td>1059.70</td>
<td>37.70</td>
<td>PKU Anamix Junior [SB]</td>
</tr>
<tr>
<td>8555G</td>
<td>4</td>
<td>5</td>
<td>..</td>
<td>1058.96</td>
<td>37.70</td>
<td>PKU gel [VF]</td>
</tr>
<tr>
<td>8591E</td>
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<td>5</td>
<td>..</td>
<td>1549.48</td>
<td>37.70</td>
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<td>1549.78</td>
<td>37.70</td>
<td>Lophex [SB]</td>
</tr>
<tr>
<td>8613H</td>
<td>4</td>
<td>5</td>
<td>..</td>
<td>892.44</td>
<td>37.70</td>
<td>PKU Anamix Junior [SB]</td>
</tr>
<tr>
<td>8727H</td>
<td>3</td>
<td>5</td>
<td>..</td>
<td>1512.40</td>
<td>37.70</td>
<td>XP Maxamum [SB]</td>
</tr>
<tr>
<td>2738D</td>
<td>8</td>
<td>5</td>
<td>..</td>
<td>884.36</td>
<td>37.70</td>
<td>XP Maxamaid [SB]</td>
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<tr>
<td>2739E</td>
<td>8</td>
<td>5</td>
<td>..</td>
<td>1352.76</td>
<td>37.70</td>
<td>XP Maxamum [SB]</td>
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<tr>
<td>2806Q</td>
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<td>5</td>
<td>..</td>
<td>1853.08</td>
<td>37.70</td>
<td>PKU Lophex Sensation 20 [SB]</td>
</tr>
</tbody>
</table>

**AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT PHENYLALANINE**

Restricted benefit
Phenylketonuria

Note: Changes in vitamin D levels and amino acid composition have occurred with a recent formulation change.

**AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT PHENYLALANINE AND TYROSINE**

Restricted benefit
Tyrosinaemia
**AMINO ACID FORMULA with VITAMINS and MINERALS without PHENYLALANINE and TYROSINE**

**Oral liquid**

125 mL, 30, 1

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
</tr>
</thead>
<tbody>
<tr>
<td>TYR Lophlex LQ 20 [SB]</td>
<td>3</td>
<td>5</td>
<td>*3098.68</td>
<td>37.70</td>
<td></td>
</tr>
</tbody>
</table>

**Tyrosinaemia**

Changes in vitamin D levels and amino acid composition have occurred with a recent formulation change.

**AMINO ACID FORMULA with VITAMINS and MINERALS without PHENYLALANINE and TYROSINE Oral liquid, 30 x 130 mL cans**

3098.68

**TYR cooler 15 [VF]**

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
</tr>
</thead>
<tbody>
<tr>
<td>TYR cooler 15 [VF]</td>
<td>4</td>
<td>5</td>
<td>*4082.72</td>
<td>37.70</td>
<td></td>
</tr>
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</table>

**AMINO ACID FORMULA with VITAMINS and MINERALS without PHENYLALANINE and TYROSINE Oral liquid, 30 x 174 mL sachets**

3098.72

**TYR cooler 20 [VF]**

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
</tr>
</thead>
<tbody>
<tr>
<td>TYR cooler 20 [VF]</td>
<td>4</td>
<td>5</td>
<td>*2114.72</td>
<td>37.70</td>
<td></td>
</tr>
</tbody>
</table>

**AMINO ACID FORMULA with VITAMINS and MINERALS without PHENYLALANINE and TYROSINE Oral liquid, 30 x 87 mL sachets**

**TYR express 15 [VF]**

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
</tr>
</thead>
<tbody>
<tr>
<td>TYR express 15 [VF]</td>
<td>4</td>
<td>5</td>
<td>*1800.80</td>
<td>37.70</td>
<td></td>
</tr>
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</table>

**AMINO ACID FORMULA with VITAMINS and MINERALS without PHENYLALANINE and TYROSINE Oral liquid: powder for, 30 x 24 g sachets**

**TYR gel [VF]**

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
</tr>
</thead>
<tbody>
<tr>
<td>TYR gel [VF]</td>
<td>4</td>
<td>5</td>
<td>*2114.72</td>
<td>37.70</td>
<td></td>
</tr>
</tbody>
</table>

**AMINO ACID FORMULA with VITAMINS and MINERALS without PHENYLALANINE and TYROSINE Oral liquid: powder for, 30 x 25 g sachets**

**TYR express 15 [VF]**

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
</tr>
</thead>
<tbody>
<tr>
<td>TYR express 15 [VF]</td>
<td>4</td>
<td>5</td>
<td>*3098.72</td>
<td>37.70</td>
<td></td>
</tr>
</tbody>
</table>

**AMINO ACID FORMULA with VITAMINS and MINERALS without PHENYLALANINE and TYROSINE Oral liquid: powder for, 30 x 29 g sachets**

**TYR Anamix Junior [SB]**

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
</tr>
</thead>
<tbody>
<tr>
<td>TYR Anamix Junior [SB]</td>
<td>4</td>
<td>5</td>
<td>*2705.08</td>
<td>37.70</td>
<td></td>
</tr>
</tbody>
</table>

**AMINO ACID FORMULA with VITAMINS and MINERALS without PHENYLALANINE and TYROSINE Oral liquid: powder for, 500 g**

**XPhen, Tyr Maxamaid [SB]**

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
</tr>
</thead>
<tbody>
<tr>
<td>XPhen, Tyr Maxamaid [SB]</td>
<td>8</td>
<td>5</td>
<td>*1785.08</td>
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**Restricted benefit**
Maple syrup urine disease

**AMINO ACID FORMULA with VITAMINS and MINERALS without VALINE, LEUCINE and ISOLEUCINE** Oral liquid

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>1546J</td>
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<td></td>
<td>3098.68</td>
<td>37.70</td>
<td>MSUD Lophlex LQ 20 [SB]</td>
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</table>

**AMINO ACID FORMULA with VITAMINS and MINERALS without VALINE, LEUCINE and ISOLEUCINE** Sachets

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>1914R</td>
<td></td>
<td></td>
<td>*4094.48</td>
<td>37.70</td>
<td>MSUD express 20 [VF]</td>
</tr>
</tbody>
</table>

**AMINO ACID FORMULA with VITAMINS and MINERALS without VALINE, LEUCINE and ISOLEUCINE** Oral liquid: powder for, 30 x 24 g sachets

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
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<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>2375B</td>
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<td>3098.72</td>
<td>37.70</td>
<td>MSUD cooler 15 [VF]</td>
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</table>

**AMINO ACID FORMULA with VITAMINS and MINERALS without VALINE, LEUCINE and ISOLEUCINE** Oral liquid: powder for, 30 x 25 g sachets

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>2651M</td>
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<td>2114.72</td>
<td>37.70</td>
<td>MSUD cooler 10 [VF]</td>
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**AMINO ACID FORMULA with VITAMINS and MINERALS without VALINE, LEUCINE and ISOLEUCINE** Oral liquid: powder for, 30 x 29 g sachets

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>8592F</td>
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<td></td>
<td>2114.72</td>
<td>37.70</td>
<td>MSUD gel [VF]</td>
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</table>

**AMINO ACID FORMULA with VITAMINS and MINERALS without VALINE, LEUCINE and ISOLEUCINE** Oral liquid: powder for, 400 g

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tr>
<td>8745G</td>
<td></td>
<td></td>
<td>1800.80</td>
<td>37.70</td>
<td>MSUD Anamix Junior [SB]</td>
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</tbody>
</table>

**AMINO ACID FORMULA with VITAMINS and MINERALS without VALINE, LEUCINE and ISOLEUCINE** Oral liquid: powder for, 500 g

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>8057C</td>
<td></td>
<td></td>
<td>769.64</td>
<td>37.70</td>
<td>MSUD Anamix infant [SB]</td>
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</tbody>
</table>

**AMINO ACID FORMULA with VITAMINS and MINERALS without VALINE, LEUCINE and ISOLEUCINE** Oral liquid: powder for, 500 g

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>8260R</td>
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<td></td>
<td>2705.08</td>
<td>37.70</td>
<td>MSUD Maxamaid [SB]</td>
</tr>
</tbody>
</table>

**AMINO ACID FORMULA with VITAMINS and MINERALS without VALINE, LEUCINE and ISOLEUCINE** Oral liquid: powder for, 500 g

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>8310J</td>
<td></td>
<td></td>
<td>2672.32</td>
<td>37.70</td>
<td>MSUD AID III [SB]</td>
</tr>
</tbody>
</table>

**AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT VALINE, LEUCINE AND ISOLEUCINE**

**Restricted benefit**
Maple syrup urine disease

Note
Changes in vitamin D levels and amino acid composition have occurred with a recent formulation change.

### Amino Acid Formula with Vitamins and Minerals without Valine, Leucine and Isoleucine

#### Oral Liquid: Powder for 30 x 36 g Sachets

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
</tr>
</thead>
<tbody>
<tr>
<td>MSUD Anamix Junior [SB]</td>
<td>4</td>
<td>5</td>
<td>..</td>
<td>2114.72</td>
<td>37.70</td>
</tr>
</tbody>
</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**

Maple syrup urine disease

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
</tr>
</thead>
<tbody>
<tr>
<td>MSUD Anamix Junior LQ [SB]</td>
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<td>5</td>
<td>..</td>
<td>2508.32</td>
<td>37.70</td>
</tr>
</tbody>
</table>

#### AMINO ACID FORMULA WITH VITAMINS, MINERALS AND LONG CHAIN POLYUNSATURATED FATTY ACIDS WITHOUT PHENYLALANINE

**Restricted benefit**

Phenylketonuria

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
</tr>
</thead>
<tbody>
<tr>
<td>PKU Anamix infant [SB]</td>
<td>8</td>
<td>5</td>
<td>..</td>
<td>703.96</td>
<td>37.70</td>
</tr>
</tbody>
</table>

#### AMINO ACID FORMULA WITHOUT PHENYLALANINE

**Restricted benefit**

Phenylketonuria

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phlexy-10 [SB]</td>
<td>24</td>
<td>5</td>
<td>..</td>
<td>1427.32</td>
<td>37.70</td>
</tr>
</tbody>
</table>

#### AMINO ACID FORMULA WITHOUT PHENYLALANINE 500 mg Capsule, 200

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phlexy-10 [SB]</td>
<td>16</td>
<td>5</td>
<td>..</td>
<td>1276.68</td>
<td>37.70</td>
</tr>
</tbody>
</table>

#### AMINO ACID FORMULA WITHOUT PHENYLALANINE ORAL LIQUID: POWDER FOR, 30 X 20 G SACHETS

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phlexy-10 Drink Mix [SB]</td>
<td>7</td>
<td>5</td>
<td>..</td>
<td>1463.25</td>
<td>37.70</td>
</tr>
</tbody>
</table>

#### AMINO ACID FORMULA WITHOUT VALINE, LEUCINE AND ISOLEUCINE

**Restricted benefit**

Maple syrup urine disease

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
</tr>
</thead>
<tbody>
<tr>
<td>MSUD amino5 [VF]</td>
<td>12</td>
<td>5</td>
<td>..</td>
<td>3098.68</td>
<td>37.70</td>
</tr>
</tbody>
</table>

#### ARACHIDONIC ACID AND DOCOSAHEXAENOIC ACID WITH CARBOHYDRATE

**Authority required**

Peroxisomal biogenesis disorders

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
</tr>
</thead>
<tbody>
<tr>
<td>keyomega [VF]</td>
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<td>5</td>
<td>..</td>
<td>371.16</td>
<td>37.70</td>
</tr>
</tbody>
</table>
**Urea cycle disorders**

**Note**
Arginine with carbohydrate is not indicated for the treatment of arginase deficiency and other inborn errors of protein metabolism.

**arginine with carbohydrate containing 2 g arginine oral liquid: powder for, 30 x 4 g sachets**

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>5482M</td>
<td>4</td>
<td>5</td>
<td></td>
<td>...</td>
<td>*771.16 37.70 Arginine 2000 [VF]</td>
</tr>
</tbody>
</table>

**arginine with carbohydrate containing 5 g arginine oral liquid: powder for, 30 x 7.6 g sachets**

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>10093F</td>
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<td>5</td>
<td></td>
<td>...</td>
<td>*1023.44 37.70 Arginine 5000 [VF]</td>
</tr>
</tbody>
</table>

**arginine with carbohydrate containing 500 mg arginine oral liquid: powder for, 30 x 4 g sachets**

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>9437Q</td>
<td>4</td>
<td>5</td>
<td></td>
<td>...</td>
<td>*516.36 37.70 Arginine 500 [VF]</td>
</tr>
</tbody>
</table>

**CARBOHYDRATE, FAT, VITAMINS, MINERALS AND TRACE ELEMENTS**

**Restricted benefit**
Proven inborn errors of protein metabolism

**Clinical criteria:**
Patient must be unable to meet their energy requirements with permitted food and formulae.

**carbohydrate, fat, vitamins, minerals and trace elements oral liquid: powder for, 400 g**

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>8369L</td>
<td>8</td>
<td>5</td>
<td></td>
<td>...</td>
<td>*318.52 37.70 Energivit [SB]</td>
</tr>
</tbody>
</table>

**CARBOHYDRATES, FAT, VITAMINS, MINERALS, TRACE ELEMENTS AND SUPPLEMENTED WITH ARACHIDONIC ACID AND DOCOSAHEXAENOIC ACID**

**Restricted benefit**
Proven inborn errors of protein metabolism

**Clinical criteria:**
Patient must be unable to meet their energy requirements with permitted food and formulae.

**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**

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>10050Y</td>
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<td>...</td>
<td>*248.60 37.70 basecal 100 [VF]</td>
</tr>
</tbody>
</table>

**carbohydrates, fat, vitamins, minerals, trace elements and supplemented with arachidonic acid and docosahexaenoic acid providing 200 kilocalories oral liquid: powder for, 30 x 43 g sachets**

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>10039J</td>
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<td></td>
<td>...</td>
<td>*472.48 37.70 basecal 200 [VF]</td>
</tr>
</tbody>
</table>

**CITRULLINE WITH CARBOHYDRATE**

**Restricted benefit**
Urea cycle disorders in order to prevent low plasma arginine or citrulline levels

**Note**
Citrulline with carbohydrate is not indicated for the treatment of arginase deficiency and other inborn errors of protein metabolism.

**citrulline with carbohydrate containing 1 g citrulline oral liquid: powder for, 30 x 4 g sachets**

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
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<tr>
<td>5481L</td>
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<td>*516.36 37.70 Citrulline 1000 [VF]</td>
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</tbody>
</table>

**CYSTINE WITH CARBOHYDRATE**

**Restricted benefit**
Pyridoxine non-responsive homocystinuria

cystine with carbohydrate containing 500 mg cystine oral liquid: powder for, 30 x 4 g sachets

<table>
<thead>
<tr>
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<tr>
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<td>...</td>
<td>*516.36 37.70 Cystine 500 [VF]</td>
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</table>

**DOCOSAHEXAENOIC ACID WITH CARBOHYDRATE**

**Authority required**
Peroxisomal biogenesis disorders
various

Schedule of Pharmaceutical Benefits

General

**VARIous**

docosahexaenoic acid with carbohydrate containing 200 mg docosahexaenoic acid oral liquid: powder for, 30 x 4 g sachets

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
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<th>MRVSN $</th>
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<tr>
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<td>..</td>
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<td>doomega [VF]</td>
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</tbody>
</table>

- **ESSENTIAL AMINO ACIDS FORMULA**
  - Restricted benefit
  - Gyrate atrophy of the choroid and retina
  - Urea cycle disorders

essential amino acids formula oral liquid: powder for, 2 x 200 g cans

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
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<tr>
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<td>1200.88</td>
<td>Essential Amino Acid Mix [SB]</td>
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</table>

- **ESSENTIAL AMINO ACIDS FORMULA WITH MINERALS AND VITAMIN C**
  - Restricted benefit
  - Gyrate atrophy of the choroid and retina
  - Urea cycle disorders

essential amino acids formula with minerals and vitamin C oral liquid: powder for, 400 g

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
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<tr>
<td>2027Q</td>
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<td>..</td>
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<td>Dialamine [SB]</td>
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</table>

- **ESSENTIAL AMINO ACIDS FORMULA WITH VITAMINS AND MINERALS**
  - Restricted benefit
  - Gyrate atrophy of the choroid and retina
  - Urea cycle disorders

essential amino acids formula with vitamins and minerals oral liquid: powder for, 50 x 12.5 g sachets

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
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<tr>
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</table>

- **GLYCINE WITH CARBOHYDRATE**
  - Restricted benefit
  - Isovaleric acidaemia

glycine with carbohydrate containing 500 mg of glycine oral liquid: powder for, 30 x 4 g sachets

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
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</table>

- **GLYCOMACROPEPTIDE AND ESSENTIAL AMINO ACIDS**
  - Restricted benefit
  - Phenylketonuria

glycomacropeptide and essential amino acids oral liquid, 12 x 500 mL bottles

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
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<td>2712R</td>
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- **GLYCOMACROPEPTIDE AND ESSENTIAL AMINO ACIDS WITH VITAMINS AND MINERALS**
  - Restricted benefit
  - Phenylketonuria

glycomacropeptide and essential amino acids with vitamins and minerals bar, 7 x 54 g

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
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<td>Camino Pro Complete [QH]</td>
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</table>

glycomacropeptide and essential amino acids with vitamins and minerals bar, 7 x 81 g

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
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<tr>
<td>2644E</td>
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<td>1296.86</td>
<td>Camino Pro Complete [QH]</td>
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</table>
glycomacropeptide and essential amino acids with vitamins and minerals oral liquid: powder for, 28 x 49 g sachets

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>2685H</th>
<th>10185C</th>
<th>2652N</th>
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<td>5</td>
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<td>*1480.12</td>
<td>37.70</td>
<td>Camino Pro Bettermilk [QH]</td>
<td>*987.31</td>
<td>37.70</td>
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</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 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 11, may be authorised.

**KetoCal 3:1**

- **Restricted benefit**
- **Clinical criteria:**
  - Patient must have intractable seizures requiring treatment with a ketogenic diet; OR
  - Patient must have a glucose transport protein defect; OR
  - Patient must have pyruvate dehydrogenase deficiency.

KetoCal 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.

**KetoCal 4:1**

- **Restricted benefit**
- **Clinical criteria:**
  - Patient must have intractable seizures requiring treatment with a ketogenic diet; OR
  - Patient must have a glucose transport protein defect; OR
  - Patient must have pyruvate dehydrogenase deficiency.

KetoCal 4:1 should only be used under strict supervision of a dietitian, together with a metabolic physician and/or neurologist.

**Note**
Authorities for increased maximum quantities, up to a maximum of 48, may be authorised.

**KetoCal 3:1**

- **Restricted benefit**
- **Clinical criteria:**
  - Patient must have intractable seizures requiring treatment with a ketogenic diet; OR
  - Patient must have a glucose transport protein defect; OR
  - Patient must have pyruvate dehydrogenase deficiency.

KetoCal 4:1 should only be used under strict supervision of a dietitian, together with a metabolic physician and/or neurologist.

**Note**
Authorities for increased maximum quantities, up to a maximum of 48, may be authorised.

**Maple syrup urine disease**

- **Restricted benefit**
- **Clinical criteria:**
  - Patient must have intractable seizures requiring treatment with a ketogenic diet; OR
  - Patient must have a glucose transport protein defect; OR
  - Patient must have pyruvate dehydrogenase deficiency.

KetoCal 4:1 should only be used under strict supervision of a dietitian, together with a metabolic physician and/or neurologist.

**Note**
Authorities for increased maximum quantities, up to a maximum of 48, may be authorised.
isoleucine with carbohydrate containing 1 g isoleucine oral liquid: powder for, 30 x 4 g sachets

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
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<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
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<td>*567.32</td>
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<td>Isoleucine 1000 [VF]</td>
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</table>

isoleucine with carbohydrate containing 50 mg isoleucine oral liquid: powder for, 30 x 4 g sachets

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
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<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>4</td>
<td>5</td>
<td>..</td>
<td>*516.36</td>
<td>37.70</td>
<td>Isoleucine 50 [VF]</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
- Glucose transport protein defects
- Pyruvate dehydrogenase deficiency

Infants and young children with glucose-galactose intolerance and multiple monosaccharide intolerance

milk protein and fat formula with vitamins and minerals carbohydrate free oral liquid: powder for, 225 g

<table>
<thead>
<tr>
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**PHENYLALANINE WITH CARBOHYDRATE**

Tyrosinaemia

phenylalanine with carbohydrate containing 50 mg phenylalanine oral liquid: powder for, 30 x 4 g sachets

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
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<th>DPMQ $</th>
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<td>Phenylalanine 50 [VF]</td>
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</table>

**SOY PROTEIN AND FAT FORMULA WITH VITAMINS AND MINERALS CARBOHYDRATE FREE**

Restricted benefit
- Patients with intractable seizures requiring treatment with a ketogenic diet
- Glucose transport protein defects
- Pyruvate dehydrogenase deficiency

Infants and young children with glucose-galactose intolerance and multiple monosaccharide intolerance

soy protein and fat formula with vitamins and minerals carbohydrate free oral liquid, 1 x 384 mL can

<table>
<thead>
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<tr>
<td>120</td>
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**TRIGLYCERIDES LONG CHAIN WITH GLUCOSE POLYMER**

Restricted benefit
- Proven inborn errors of protein metabolism

Clinical criteria:
- Patient must be unable to meet their energy requirements with permitted food and formulae.

triglycerides long chain with glucose polymer oral liquid, 27 x 200 mL cartons

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
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<tr>
<td>2</td>
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<td>*192.18</td>
<td>37.70</td>
<td>Sno-Pro [SB]</td>
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</table>

**TRIGLYCERIDES LONG CHAIN WITH GLUCOSE POLYMER**

Restricted benefit
- Patients with proven inborn errors of protein metabolism who are unable to meet their energy requirements with permitted food and formulae.

triglycerides long chain with glucose polymer oral liquid, 18 x 250 mL cans

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
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<td>ProZero [VF]</td>
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<td>Tyrosine 1000 [VF]</td>
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<td>Valine 50 [VF]</td>
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</tr>
</tbody>
</table>

### TRIGLYCERIDES MEDIUM CHAIN FORMULA

**Restricted benefit**

Patients with proven inborn errors of protein metabolism who are unable to meet their energy requirements with permitted food and formulae.

- Fat malabsorption due to liver disease, short gut syndrome, cystic fibrosis and gastrointestinal disorders
- Hyperlipoproteinaemia type 1
- Long chain fatty acid oxidation disorders

**Note**

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

MCT Pro-Cal is not indicated for the treatment of intractable childhood epilepsy or cerebrospinal fluid glucose transporter defect requiring a ketogenic diet.

### TYROSINE WITH CARBOHYDRATE

**Restricted benefit**

Phenylketonuria

- Maple syrup urine disease

### VALINE WITH CARBOHYDRATE

**Restricted benefit**

- Maple syrup urine disease

### VITAMINS, MINERALS AND TRACE ELEMENTS WITH CARBOHYDRATE

**Authority required**

Dietary management of conditions requiring a highly restrictive therapeutic diet

**Clinical criteria:**

- Patient must have insufficient vitamin and mineral intake due to a specific diagnosis requiring a highly restrictive therapeutic diet.
- Patient must be unable to adequately meet vitamin, mineral and trace element needs with other proprietary vitamin and mineral preparations.

**Population criteria:**

- Patient must be aged 3 years or older.

**Note**

FruitiVits must only be used under strict supervision of a dietitian and a paediatrician.
VITAMINS, MINERALS AND TRACE ELEMENTS WITH CARBOHYDRATE

**Authority required**
Dietary management of conditions requiring a highly restrictive therapeutic diet

**Clinical criteria:**
- Patient must have insufficient vitamin and mineral intake due to a specific diagnosis requiring a highly restrictive therapeutic diet, **AND**
- Patient must be unable to adequately meet vitamin, mineral and trace element needs with other proprietary vitamin and mineral preparations.

**Population criteria:**
- Patient must be an infant or a child.

---

**Note**
Paediatric Seravit must only be used under strict supervision of a dietitian and a paediatrician.

---

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.
Palliative Care

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## STOMATOLOGICAL PREPARATIONS

**Other agents for local oral treatment**

### BENZYDAMINE

**Authority required (STREAMLINED)**

3634

Initial supply, for up to 4 months, for a palliative care patient where a painful mouth is a problem

<table>
<thead>
<tr>
<th>benzydamine hydrochloride 0.15% mouthwash, 500 mL</th>
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</thead>
<tbody>
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<tr>
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<tr>
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### BENZYDAMINE

**Authority required (STREAMLINED)**

3635

Continuing supply for a palliative care patient where a painful mouth 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>benzydamine hydrochloride 0.15% mouthwash, 500 mL</th>
</tr>
</thead>
<tbody>
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</tr>
<tr>
<td>---------------</td>
</tr>
<tr>
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## DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS

### BELLADONNA AND DERIVATIVES, PLAIN

Belladonna alkaloids, semisynthetic, quaternary ammonium compounds

### HYOSCINE BUTYLBROMIDE

**Authority required (STREAMLINED)**

3638

Initial supply, for up to 4 months, for a palliative care patient where colicky pain is a symptom

<table>
<thead>
<tr>
<th>hyoscine butylbromide 20 mg/mL injection, 5 x 1 mL ampoules</th>
</tr>
</thead>
<tbody>
<tr>
<td>Max Qty Packs</td>
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</tr>
<tr>
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### HYOSCINE BUTYLBROMIDE

**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.

<table>
<thead>
<tr>
<th>hyoscine butylbromide 20 mg/mL injection, 5 x 1 mL ampoules</th>
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## DRUGS FOR CONSTIPATION

### 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
### ALIMENTARY TRACT AND METABOLISM

#### Schedule of Pharmaceutical Benefits

<table>
<thead>
<tr>
<th>Product Description</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
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<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
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<tr>
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<td>3</td>
<td>3</td>
<td>21.28</td>
<td>22.43</td>
<td>*Petrus Bisacodyl Suppositories [PP]</td>
<td></td>
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<tr>
<td><strong>bisacodyl 10 mg suppository, 12</strong></td>
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<td>3</td>
<td>18.67</td>
<td>19.82</td>
<td>*Petrus Bisacodyl Suppositories [PP]</td>
<td></td>
</tr>
<tr>
<td><strong>bisacodyl 5 mg tablet: enteric, 200 tablets</strong></td>
<td>1</td>
<td>3</td>
<td>14.45</td>
<td>15.60</td>
<td>Bisalax [AS] Lax-Tab [AE]</td>
<td></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>Product Description</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>bisacodyl 10 mg suppository, 10</strong></td>
<td>3</td>
<td>3</td>
<td>21.28</td>
<td>22.43</td>
<td>*Petrus Bisacodyl Suppositories [PP]</td>
<td></td>
</tr>
<tr>
<td><strong>bisacodyl 10 mg suppository, 12</strong></td>
<td>3</td>
<td>3</td>
<td>18.67</td>
<td>19.82</td>
<td>*Petrus Bisacodyl Suppositories [PP]</td>
<td></td>
</tr>
<tr>
<td><strong>bisacodyl 5 mg tablet: enteric, 200 tablets</strong></td>
<td>1</td>
<td>3</td>
<td>14.45</td>
<td>15.60</td>
<td>Bisalax [AS] Lax-Tab [AE]</td>
<td></td>
</tr>
</tbody>
</table>

**RHAMNUS FRANGULA + STERCULIA**

**Authority required (STREAMLINED)**

**3642**

Initial supply, for up to 4 months, for a palliative care patient where constipation is a problem.

<table>
<thead>
<tr>
<th>Product Description</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>rhamnus frangula 80 mg/g + sterculia 620 mg/g granules, 500 g</strong></td>
<td>1</td>
<td>3</td>
<td>26.71</td>
<td>27.86</td>
<td>Normacol Plus [NE]</td>
<td></td>
</tr>
</tbody>
</table>

**RHAMNUS FRANGULA + STERCULIA**

**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>Product Description</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>rhamnus frangula 80 mg/g + sterculia 620 mg/g granules, 500 g</strong></td>
<td>1</td>
<td>3</td>
<td>26.71</td>
<td>27.86</td>
<td>Normacol Plus [NE]</td>
<td></td>
</tr>
</tbody>
</table>

**LACTULOSE**

**Authority required (STREAMLINED)**

**3642**

Initial supply, for up to 4 months, for a palliative care patient where constipation is a problem.
LACTULOSE Mixture 3.34 g per 5 mL, 500 mL, 1

5387M

Max Qty Packs  No. of Rpts  Premium $  DPMQ $  MRVSN $  Brand Name and Manufacturer  Brand Name and Manufacturer
3  3  .  *18.58  19.73  a Genlac [QA]  a Dulose [FM]

LACTULOSE

 Authority required (STREAMLINED)

3643

Continuing supply for a palliative care patient where constipation is a problem

Note

Written or telephone authority applications for increased repeats may be approved where consultation with a palliative care specialist or service has occurred.

LACTULOSE Mixture 3.34 g per 5 mL, 500 mL, 1

5388N

Max Qty Packs  No. of Rpts  Premium $  DPMQ $  MRVSN $  Brand Name and Manufacturer  Brand Name and Manufacturer
3  3  .  *18.58  19.73  a Genlac [QA]  a Dulose [FM]

MACROGOL-3350

 Authority required (STREAMLINED)

4176

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.

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.

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

2351R

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

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

5426N

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

MACROGOL-3350

 Authority required (STREAMLINED)

4170

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.

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.

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

2353W

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

macrogol-3350 + SODIUM CHLORIDE + POTASSIUM CHLORIDE + BICARBONATE

 Authority required (STREAMLINED)

4595

Constipation

Note

Written or telephone authority applications for increased repeats may be approved where consultation with a palliative care specialist or service has occurred.
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.

**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**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>5389P</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>*30.38 APO-MACROGOL plus ELECTROLYTES [TX] LaxaCon [GN]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>*31.53 lax-sachets [AE] Macrovia [QA]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Molaxole [HM] Movicol [NE]</td>
</tr>
</tbody>
</table>

**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**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>10127B</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>*22.52 Movicol Liquid [NE]</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.

**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**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
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<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>5390Q</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>*30.38 APO-MACROGOL plus ELECTROLYTES [TX] LaxaCon [GN]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>*31.53 lax-sachets [AE] Macrovia [QA]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Molaxole [HM] Movicol [NE]</td>
</tr>
</tbody>
</table>

**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**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
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<tbody>
<tr>
<td>10112F</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>*22.52 Movicol Liquid [NE]</td>
</tr>
</tbody>
</table>

### Enemas

**BISACODYL**

**Authority required (STREAMLINED)**

**3642**
Initial supply, for up to 4 months, for a palliative care patient where constipation is a problem

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

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
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<tbody>
<tr>
<td>5302C</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>*38.28 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.

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

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>5306G</td>
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<td></td>
<td></td>
<td></td>
<td>*38.28 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

**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.

**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.

Special Pricing Arrangements apply.

**GLYCEROL**

**Authority required (STREAMLINED)**

3642

Initial supply, for up to 4 months, for a palliative care patient where constipation is a problem

**Other drugs for constipation**

**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 failed to respond to laxatives

**Note**

No applications for repeats will be authorised.

Special Pricing Arrangements apply.
### GLYCEROL

**Authority required (STREAMLINED) 3643**

Continuing supply for a palliative care patient where constipation is a problem

**Note**

Written or telephone authority applications for increased repeats may be approved where consultation with a palliative care specialist or service has occurred.

<table>
<thead>
<tr>
<th>Item Description</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium</th>
<th>DPMQ</th>
<th>MRVSN</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>glycerol 700 mg suppository, 12</td>
<td>3</td>
<td>3</td>
<td>..</td>
<td><strong>21.10</strong></td>
<td><strong>22.25</strong></td>
<td>Petrus Pharmaceuticals Pty Ltd [PP]</td>
</tr>
<tr>
<td>glycerol 1.4 g suppository, 12</td>
<td>3</td>
<td>..</td>
<td>..</td>
<td><strong>21.55</strong></td>
<td><strong>22.70</strong></td>
<td>Petrus Pharmaceuticals Pty Ltd [PP]</td>
</tr>
<tr>
<td>glycerol 2.8 g suppository, 12</td>
<td>3</td>
<td>..</td>
<td>..</td>
<td><strong>22.15</strong></td>
<td><strong>23.30</strong></td>
<td>Petrus Pharmaceuticals Pty Ltd [PP]</td>
</tr>
<tr>
<td>glycerol 700 mg suppository, 12</td>
<td>3</td>
<td>..</td>
<td>..</td>
<td><strong>21.10</strong></td>
<td><strong>22.25</strong></td>
<td>Petrus Pharmaceuticals Pty Ltd [PP]</td>
</tr>
</tbody>
</table>

### MUSCULO-SKELETAL SYSTEM

### ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS

#### ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS

Acetic acid derivatives and related substances

### 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>Item Description</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium</th>
<th>DPMQ</th>
<th>MRVSN</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>diclofenac sodium 25 mg tablet: enteric, 50 tablets</td>
<td>2</td>
<td>3</td>
<td>..</td>
<td><strong>10.62</strong></td>
<td><strong>11.77</strong></td>
<td>APO-Diclofenac [TX]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Clonac 25 [QA]</td>
</tr>
<tr>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td>Diclofenac-GA [GN]</td>
</tr>
<tr>
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<td></td>
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<td></td>
<td>Fenac 25 [AF]</td>
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<td></td>
<td>Chlorfenam [CN]</td>
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<tr>
<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>Voltaren 25 [NV]</td>
</tr>
</tbody>
</table>

### 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>Item Description</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium</th>
<th>DPMQ</th>
<th>MRVSN</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>diclofenac sodium 100 mg suppository, 20</td>
<td>2</td>
<td>3</td>
<td>..</td>
<td><strong>25.26</strong></td>
<td><strong>26.41</strong></td>
<td>Voltaren 100 [NV]</td>
</tr>
</tbody>
</table>
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.

### DILOFENAC

**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.

### DICLOFENAC

**diclofenac sodium 25 mg tablet: enteric, 50 tablets**

<table>
<thead>
<tr>
<th>5364H</th>
<th>Max Qty</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
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</thead>
<tbody>
<tr>
<td>2</td>
<td>..</td>
<td>..</td>
<td>10.62</td>
<td>11.77</td>
<td></td>
</tr>
</tbody>
</table>

* APO-Diclofenac [TX]
* Clonac 25 [QA]
* Diclofenac-GA [GN]
* Fenac 25 [AF]

**diclofenac sodium 50 mg tablet: enteric, 50 tablets**

<table>
<thead>
<tr>
<th>5365J</th>
<th>Max Qty</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
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<tbody>
<tr>
<td>1</td>
<td>..</td>
<td>..</td>
<td>9.44</td>
<td>10.59</td>
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</table>

* APO-Diclofenac [TX]
* Clonac 50 [QA]
* Diclofenac-GA [GN]
* Fenac [AF]

**diclofenac sodium 100 mg suppository, 20**

<table>
<thead>
<tr>
<th>5366K</th>
<th>Max Qty</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>..</td>
<td>..</td>
<td>25.26</td>
<td>26.41</td>
<td></td>
</tr>
</tbody>
</table>

* Voltaren 100 [NV]

### INDOMETHACIN

**Authority required (STREAMLINED)**

3645
Initial supply, for up to 4 months, for a palliative care patient where severe pain is a problem

### indomethacin 25 mg capsule, 50

<table>
<thead>
<tr>
<th>5377B</th>
<th>Max Qty</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
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<tbody>
<tr>
<td>2</td>
<td>3</td>
<td>..</td>
<td>13.20</td>
<td>14.35</td>
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* Arthrexin [AF]

**indomethacin 100 mg suppository, 20**

<table>
<thead>
<tr>
<th>5378C</th>
<th>Max Qty</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
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<tbody>
<tr>
<td>2</td>
<td>3</td>
<td>..</td>
<td>22.84</td>
<td>23.99</td>
<td></td>
</tr>
</tbody>
</table>

* Indocid [AS]

### 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.

### indomethacin 25 mg capsule, 50

<table>
<thead>
<tr>
<th>5379D</th>
<th>Max Qty</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
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</thead>
<tbody>
<tr>
<td>2</td>
<td>..</td>
<td>..</td>
<td>13.20</td>
<td>14.35</td>
<td></td>
</tr>
</tbody>
</table>

* Arthrexin [AF]

**indomethacin 100 mg suppository, 20**

<table>
<thead>
<tr>
<th>5378C</th>
<th>Max Qty</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
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<tr>
<td>2</td>
<td>3</td>
<td>..</td>
<td>22.84</td>
<td>23.99</td>
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</tbody>
</table>

* Indocid [AS]

**indomethacin 25 mg capsule, 50**

<table>
<thead>
<tr>
<th>5379D</th>
<th>Max Qty</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
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</thead>
<tbody>
<tr>
<td>2</td>
<td>..</td>
<td>..</td>
<td>13.20</td>
<td>14.35</td>
<td></td>
</tr>
</tbody>
</table>

* Arthrexin [AF]

**indomethacin 100 mg suppository, 20**

<table>
<thead>
<tr>
<th>5378C</th>
<th>Max Qty</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
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<tr>
<td>2</td>
<td>3</td>
<td>..</td>
<td>22.84</td>
<td>23.99</td>
<td></td>
</tr>
</tbody>
</table>

* Indocid [AS]
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.

indomethacin 100 mg suppository, 20

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Max Qty</th>
<th>Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Indocid [AS]</strong></td>
<td>2</td>
<td>..</td>
<td>..</td>
<td>22.84</td>
<td>23.99</td>
<td>*(A)</td>
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</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

ibuprofen 400 mg tablet, 30

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Max Qty</th>
<th>Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Brufen [GO]</strong></td>
<td>3</td>
<td>3</td>
<td>..</td>
<td>15.07</td>
<td>16.22</td>
<td>*(A)</td>
</tr>
</tbody>
</table>

- **IBUPROFEN**
  Authority required
  Continuing supply for a palliative care patient where severe pain is a problem

ibuprofen 400 mg tablet, 30

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Max Qty</th>
<th>Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Brufen [GO]</strong></td>
<td>3</td>
<td>..</td>
<td>..</td>
<td>15.07</td>
<td>16.22</td>
<td>*(A)</td>
</tr>
</tbody>
</table>

- **NAPROXEN**
  Authority required (STREAMLINED)

4128
Severe pain
Treatment Phase: Initial treatment
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.

naproxen 125 mg/5 mL oral liquid, 474 mL

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Max Qty</th>
<th>Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Phebra Naproxen Suspension [PL]</strong></td>
<td>1</td>
<td>3</td>
<td>..</td>
<td>127.96</td>
<td>37.70</td>
<td>*(A)</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

naproxen 1 g tablet: modified release, 28

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Max Qty</th>
<th>Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Proxin SR 1000 [MD]</strong></td>
<td>1</td>
<td>3</td>
<td>..</td>
<td>14.30</td>
<td>15.45</td>
<td>*(A)</td>
</tr>
<tr>
<td><strong>Naprosyn SR1000 [RO]</strong></td>
<td></td>
<td></td>
<td></td>
<td>1.29</td>
<td>15.59</td>
<td>15.45</td>
</tr>
</tbody>
</table>

naproxen 250 mg tablet, 50

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Max Qty</th>
<th>Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Inza 250 [AF]</strong></td>
<td>2</td>
<td>3</td>
<td>..</td>
<td>13.68</td>
<td>14.83</td>
<td>*(A)</td>
</tr>
<tr>
<td><strong>Naprosyn [RO]</strong></td>
<td></td>
<td></td>
<td></td>
<td>2.24</td>
<td>15.92</td>
<td>14.83</td>
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</table>

naproxen 500 mg tablet, 50

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
<th>Max Qty</th>
<th>Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Inza 500 [AF]</strong></td>
<td>1</td>
<td>3</td>
<td>..</td>
<td>12.94</td>
<td>14.09</td>
<td>*(A)</td>
</tr>
<tr>
<td><strong>Naprosyn [RO]</strong></td>
<td></td>
<td></td>
<td></td>
<td>1.28</td>
<td>14.22</td>
<td>14.09</td>
</tr>
</tbody>
</table>
naproxen 750 mg tablet: modified release, 28 tablets

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>5347K</td>
<td>1</td>
<td>12.42</td>
<td>13.57</td>
<td></td>
<td>Proxen SR 750 [MD]</td>
</tr>
<tr>
<td></td>
<td></td>
<td>$1.22</td>
<td>13.64</td>
<td>13.57</td>
<td>Naprosyn SR750 [RO]</td>
</tr>
</tbody>
</table>

### NAPROXEN

**Authority required (STREAMLINED)**

**3645**

Initial supply, for up to 4 months, for a palliative care patient where severe pain is a problem

**Note**

Naproxen sodium 550 mg is approximately equivalent to 500 mg of naproxen.

naproxen sodium 550 mg tablet, 50

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tr>
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<td>14.26</td>
<td></td>
<td>Cysanal [MD]</td>
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<tr>
<td></td>
<td></td>
<td>$2.17</td>
<td>15.28</td>
<td>14.26</td>
<td>Anaprox 550 [RO]</td>
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</tbody>
</table>

### NAPROXEN

**Authority required (STREAMLINED)**

**4129**

Severe pain

**Clinical criteria:**

Patient must be unable to take a solid dose form of a non-steroidal anti-inflammatory agent.

**Treatment criteria:**

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.

naproxen 125 mg/5 mL oral liquid, 474 mL

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>5398D</td>
<td>1</td>
<td>127.96</td>
<td>37.70</td>
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<td>Phebra Naproxen Suspension [PL]</td>
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</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.

naproxen 1 g tablet: modified release, 28

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
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<td>Proxen SR 1000 [MD]</td>
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<tr>
<td></td>
<td></td>
<td>$1.29</td>
<td>15.59</td>
<td>15.45</td>
<td>Naprosyn SR1000 [RO]</td>
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</tbody>
</table>

naproxen 250 mg tablet, 50

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>5349M</td>
<td>2</td>
<td>13.68</td>
<td>14.83</td>
<td></td>
<td>Inza 250 [AF]</td>
</tr>
<tr>
<td></td>
<td></td>
<td>$2.24</td>
<td>15.92</td>
<td>14.83</td>
<td>Naprosyn [RO]</td>
</tr>
</tbody>
</table>

naproxen 500 mg tablet, 50

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
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<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
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<td>14.09</td>
<td></td>
<td>Inza 500 [AF]</td>
</tr>
<tr>
<td></td>
<td></td>
<td>$1.28</td>
<td>14.22</td>
<td>14.09</td>
<td>Naprosyn [RO]</td>
</tr>
</tbody>
</table>

naproxen 750 mg tablet: modified release, 28 tablets

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
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<td>13.57</td>
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<td>Proxen SR 750 [MD]</td>
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<tr>
<td></td>
<td></td>
<td>$1.22</td>
<td>13.64</td>
<td>13.57</td>
<td>Naprosyn SR750 [RO]</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.

Naproxen sodium 550 mg is approximately equivalent to 500 mg of naproxen acid.

Naproxen sodium 550 mg tablet, 50

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>..</td>
<td>13.11</td>
<td>14.26</td>
<td>* Cysaran [MD]</td>
<td></td>
</tr>
</tbody>
</table>

MORPHINE

Caution
The risk of drug dependence is high.

Authority required
Chronic severe disabling pain
Treatment Phase: Initial treatment, for up to 3 months

Clinical criteria:
Patient must be receiving palliative care, AND
The condition must be unresponsive to non-narcotic analgesics.

Note
Telephone approvals are limited to 1 month’s therapy.

Morphine sulfate 200 mg tablet: modified release, 28 tablets

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2</td>
<td>122.20</td>
<td>37.70</td>
<td>MS Cont [MF]</td>
<td></td>
</tr>
</tbody>
</table>

MORPHINE

Caution
The risk of drug dependence is high.

Authority required
Severe disabling pain
Treatment Phase: Initial treatment, for up to 3 months

Clinical criteria:
Patient must be receiving palliative care, AND
The condition must be unresponsive to non-narcotic analgesics.

Note
Telephone approvals are limited to 1 month’s therapy.

Morphine sulfate 10 mg tablet, 20

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2</td>
<td>14.66</td>
<td>15.81</td>
<td>Sevredol [MF]</td>
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Morphine sulfate 20 mg tablet, 20

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<th>Max.Qty Packs</th>
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<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
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<td>15.60</td>
<td>16.75</td>
<td>Sevredol [MF]</td>
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</tr>
</tbody>
</table>

MORPHINE

Caution
The risk of drug dependence is high.

Authority required
Chronic severe disabling pain
Treatment Phase: Continuing treatment

Clinical criteria:
Patient must be receiving palliative care, AND
The condition must be unresponsive to non-narcotic analgesics.

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.

**morphine sulfate 200 mg tablet: modified release, 28 tablets**

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>5392T</td>
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<td>MS Contin [MF]</td>
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</tbody>
</table>

### MORPHINE

**Caution**
The risk of drug dependence is high.

**Authority required**
Severe disabling pain

**Clinical criteria:**
Patient must be receiving palliative care, **AND**
The condition must be unresponsive to non-narcotic analgesics.

**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.

**morphine sulfate 10 mg tablet, 20**

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
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**morphine sulfate 200 mg tablet, 20**

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
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<th>DPMQ $</th>
<th>MRVSN $</th>
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<td>..</td>
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<td>16.75</td>
<td>Sevredol [MF]</td>
</tr>
</tbody>
</table>

### Phenylpiperidine derivatives

### FENTANYL

**Caution**
The risk of drug dependence is high.

**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.

**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.

**FENTANYL Lozenge 1200 micrograms (as citrate), 9**

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
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<td>99.95</td>
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<td>Actiq [OA]</td>
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</table>

**FENTANYL Lozenge 1600 micrograms (as citrate), 9**

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
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<td>Actiq [OA]</td>
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**FENTANYL Lozenge 200 micrograms (as citrate), 9**

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
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FENTANYL Lozenge 400 micrograms (as citrate), 9
5402H

<table>
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<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
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<tbody>
<tr>
<td>1</td>
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<td>99.95</td>
<td>37.70</td>
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<td>Actiq [OA]</td>
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FENTANYL Lozenge 600 micrograms (as citrate), 9
5403J

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<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>1</td>
<td></td>
<td>99.95</td>
<td>37.70</td>
<td></td>
<td>Actiq [OA]</td>
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</tbody>
</table>

FENTANYL Lozenge 800 micrograms (as citrate), 9
5404K

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td></td>
<td>99.95</td>
<td>37.70</td>
<td></td>
<td>Actiq [OA]</td>
</tr>
</tbody>
</table>

FENTANYL

- **Caution**
  - The risk of drug dependence is high.
- **Authority required**
  - Breakthrough pain
  - 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.

**Note**
- For first continuing supply, applications for increased repeats for up to 3 months’ supply may be authorised.
- 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.

**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.

FENTANYL Lozenge 1200 micrograms (as citrate), 30
5411T

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td></td>
<td>*579.77</td>
<td>37.70</td>
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<td>Actiq [OA]</td>
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FENTANYL Lozenge 1600 micrograms (as citrate), 30
5412W

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<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td></td>
<td>*579.77</td>
<td>37.70</td>
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<td>Actiq [OA]</td>
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</tbody>
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FENTANYL Lozenge 200 micrograms (as citrate), 30
5407N

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td></td>
<td>*579.77</td>
<td>37.70</td>
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<td>Actiq [OA]</td>
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</tbody>
</table>

FENTANYL Lozenge 400 micrograms (as citrate), 30
5408P

<table>
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<tr>
<th>Max Qty Packs</th>
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<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
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<td>37.70</td>
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<td>Actiq [OA]</td>
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FENTANYL Lozenge 600 micrograms (as citrate), 30
5409Q

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<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
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<td>*579.77</td>
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<td>Actiq [OA]</td>
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FENTANYL Lozenge 800 micrograms (as citrate), 30
5410R

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<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td></td>
<td>*579.77</td>
<td>37.70</td>
<td></td>
<td>Actiq [OA]</td>
</tr>
</tbody>
</table>

Diphenylpropylamine derivatives

METHADONE

- **Caution**
  - The risk of drug dependence is high.
- **Authority required**
  - Chronic severe disabling pain
NERVOUS SYSTEM

Treatment Phase: Initial treatment, for up to 3 months

Clinical criteria:
Patient must be receiving palliative care, AND
The condition must be unresponsive to non-narcotic analgesics.

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.

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.

methadone hydrochloride 5 mg/mL oral liquid, 200 mL

<table>
<thead>
<tr>
<th>Max Qty</th>
<th>Packs</th>
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<th>Premium</th>
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<tbody>
<tr>
<td>5399E</td>
<td>1</td>
<td>2</td>
<td>..</td>
<td>19.25</td>
<td>20.40</td>
<td>Aspen Methadone Syrup [QA]</td>
</tr>
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</table>

- METHADONE

Caution
The risk of drug dependence is high.

Authority required
Chronic severe disabling pain

Treatment Phase: Continuing treatment

Clinical criteria:
Patient must be receiving palliative care, AND
The condition must be unresponsive to non-narcotic analgesics.

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.

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.

methadone hydrochloride 5 mg/mL oral liquid, 200 mL

<table>
<thead>
<tr>
<th>Max Qty</th>
<th>Packs</th>
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<td>5400F</td>
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<td>..</td>
<td>19.25</td>
<td>20.40</td>
<td>Aspen Methadone Syrup [QA]</td>
</tr>
</tbody>
</table>

OTHER ANALGESICS AND ANTIPYRETICS

Anilides

- PARACETAMOL

Authority required (STREAMLINED)

4940
Analgesia or fever

Treatment Phase: Initial treatment, for up to 4 months

Clinical criteria:
Patient must be receiving palliative care, AND
Patient must be intolerant to alternative therapy.

paracetamol 500 mg suppository, 24

<table>
<thead>
<tr>
<th>Max Qty</th>
<th>Packs</th>
<th>No. of Rpts</th>
<th>Premium</th>
<th>DPMQ</th>
<th>MRVSN</th>
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<tbody>
<tr>
<td>5319Y</td>
<td>4</td>
<td>3</td>
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<td>*84.80</td>
<td>37.70</td>
<td>Panadol [GC]</td>
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</table>

paracetamol 665 mg tablet: modified release, 96 tablets

<table>
<thead>
<tr>
<th>Max Qty</th>
<th>Packs</th>
<th>No. of Rpts</th>
<th>Premium</th>
<th>DPMQ</th>
<th>MRVSN</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>5343F</td>
<td>2</td>
<td>3</td>
<td>..</td>
<td>*15.34</td>
<td>16.49</td>
<td>Osteomol 665 Paracetamol [CR]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>81.64</td>
<td>16.98</td>
<td>Panadol Osteo [GC]</td>
</tr>
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</table>

- PARACETAMOL

Authority required (STREAMLINED)

4950
Analgesia or fever

Treatment Phase: Continuing treatment
Clinical criteria:
Patient must be receiving palliative care, **AND**
Patient must be intolerant to alternative therapy.

**Note**
Written or telephone authority applications for increased repeats may be approved where consultation with a palliative care specialist or service has occurred.

### paracetamol 500 mg suppository, 24

<table>
<thead>
<tr>
<th>5320B</th>
<th>Max.Qty Packs</th>
<th>No. of Rpts</th>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>*84.80</td>
<td>37.70</td>
<td>Panadol [GC]</td>
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### paracetamol 665 mg tablet: modified release, 96 tablets

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<td></td>
<td>*15.34</td>
<td>16.49</td>
<td>* Osteomol 665 Paracetamol  [CR]</td>
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<td></td>
<td></td>
<td></td>
<td>1.64</td>
<td>16.98</td>
<td>* Panadol Osteo [GC]</td>
</tr>
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### 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.

### clonazepam 2 mg tablet, 100

<table>
<thead>
<tr>
<th>5338Y</th>
<th>Max.Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
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<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>19.08</td>
<td>20.23</td>
<td>* Paxam 2 [AF]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>1.93</td>
<td>21.01</td>
<td>* Rivotril [RO]</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>5339B</th>
<th>Max.Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
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<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>*15.38</td>
<td>16.53</td>
<td>Rivotril [RO]</td>
</tr>
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</table>

### clonazepam 500 microgram tablet, 100

<table>
<thead>
<tr>
<th>5337X</th>
<th>Max.Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
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<tbody>
<tr>
<td></td>
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<td></td>
<td></td>
<td>13.30</td>
<td>14.45</td>
<td>* Paxam 0.5 [AF]</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>1.71</td>
<td>15.01</td>
<td>* Rivotril [RO]</td>
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</table>

### CLONAZEPAM

**Authority required**
Continuing supply for a palliative care patient for the prevention of epilepsy

**Note**
Where consultation with a palliative care specialist or service has occurred, applications for increased repeats may be authorised.

### clonazepam 2 mg tablet, 100

<table>
<thead>
<tr>
<th>5341D</th>
<th>Max.Qty Packs</th>
<th>No. of Rpts</th>
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<tr>
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<td>19.08</td>
<td>20.23</td>
<td>* Paxam 2 [AF]</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>1.93</td>
<td>21.01</td>
<td>* Rivotril [RO]</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>5342E</th>
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<th>No. of Rpts</th>
<th>Premium $</th>
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<tr>
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<td></td>
<td></td>
<td></td>
<td>*15.38</td>
<td>16.53</td>
<td>Rivotril [RO]</td>
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### clonazepam 500 microgram tablet, 100

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<thead>
<tr>
<th>5340C</th>
<th>Max.Qty Packs</th>
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<tbody>
<tr>
<td></td>
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<td></td>
<td></td>
<td>13.30</td>
<td>14.45</td>
<td>* Paxam 0.5 [AF]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>1.71</td>
<td>15.01</td>
<td>* Rivotril [RO]</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>Diazepam 2 mg tablet, 50</th>
</tr>
</thead>
<tbody>
<tr>
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</tr>
<tr>
<td>1</td>
</tr>
<tr>
<td></td>
</tr>
</tbody>
</table>

### DIAZEPAM

**Authority required**
Continuing supply for a palliative care patient where anxiety 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>Diazepam 2 mg tablet, 50</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Max Qty Packs</strong></td>
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<tr>
<td>2</td>
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<tr>
<td></td>
</tr>
</tbody>
</table>

### 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>Oxazepam 15 mg tablet, 25</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Max Qty Packs</strong></td>
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<tr>
<td>2</td>
</tr>
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<td></td>
</tr>
</tbody>
</table>

### OXAZEPAM

**Authority required**
Continuing supply for a palliative care patient where anxiety is a problem

**Note**
Where consultation with a palliative care specialist or service has occurred, applications for increased repeats may be authorised.
NERVOUS SYSTEM

oxazepam 15 mg tablet, 25

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium ($)</th>
<th>DPMQ ($)</th>
<th>MRVSN ($)</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>..</td>
<td>*9.24</td>
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<td>*5.36</td>
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</table>

oxazepam 30 mg tablet, 25

<table>
<thead>
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<th>No. of Rpts</th>
<th>Premium ($)</th>
<th>DPMQ ($)</th>
<th>MRVSN ($)</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>..</td>
<td>*9.24</td>
<td>10.39</td>
<td>*5.36</td>
<td>Alepam 30 [AF]</td>
</tr>
</tbody>
</table>

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.

NITRAZEPAM

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.

TEMAZEPAM

Authority required
Initial supply, for up to 4 months, for a palliative care patient where insomnia is a problem

Note
No applications for increased repeats will be authorised.

TEMAZEPAM

Authority required
Continuing supply for a palliative care patient where insomnia is a problem

Note
Where consultation with a palliative care specialist or service has occurred, applications for increased repeats may be authorised.
Highly Specialised Drugs Program
(Private Hospital)

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ELTROMBOPAG

Authority required
Initial (new patients)
Initial treatment, as the sole PBS-subsidised thrombopoietin receptor agonist (TRA), of severe thrombocytopenia in an adult patient with severe chronic immune (idiopathic) thrombocytopenic purpura (ITP) who is:
(1) Splenectomised and:
(a) has had an inadequate response to, or is intolerant to, corticosteroid therapy post splenectomy; and
(b) has had an inadequate response to, or is intolerant to, immunoglobulin therapy post splenectomy;
OR
(2) Not splenectomised and:
(a) has had an inadequate response, or is intolerant to, corticosteroid therapy at a dose equivalent to 0.5-2 mg/kg/day of prednisone for at least 4-6 weeks; and
(b) has had an inadequate response, or is intolerant to, immunoglobulin therapy; and
(c) in whom splenectomy is contraindicated for medical reasons.
The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of initial application:
(a) a platelet count of less than or equal to 20,000 million per L;
OR
(b) a platelet count of 20-30,000 million per L, where the patient is experiencing significant bleeding or has a history of significant bleeding in this platelet range.
The authority application must be made in writing and must include:
(1) a completed authority prescription form,
(2) a signed patient acknowledgement,
(3) a completed Idiopathic Thrombocytopenic Purpura Initial PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)],
(4) a copy of a full blood count pathology report supporting the diagnosis of ITP, and
(5) where the application is sought on the basis of a medical contraindication to surgery, a signed and dated letter from the clinician making this assessment which includes the date upon which the patient was assessed for surgery and the clinical grounds upon which surgery is contraindicated.
The full blood count must be no more than 1 month old at the time of application.
A maximum of 24 weeks of treatment with eltrombopag will be authorised under this criterion

Authority required
Initial (grandfather patients)
Initial treatment, as the sole PBS-subsidised thrombopoietin receptor agonist (TRA), of severe thrombocytopenia in an adult patient with severe chronic immune (idiopathic) thrombocytopenic purpura (ITP) who was receiving treatment with eltrombopag prior to 1 November 2011 and in whom the criteria for initial treatment can be demonstrated to have been met at the time eltrombopag was commenced.
The authority application must be made in writing and must include:
(1) a completed authority prescription form,
(2) a signed patient acknowledgement,
(3) a completed Idiopathic Thrombocytopenic Purpura Initial PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)], and
(4) where the application is sought on the basis of a medical contraindication to surgery, a signed and dated letter from the clinician making this assessment which includes the date upon which the patient was assessed for surgery and the clinical grounds upon which surgery is contraindicated.
A maximum of 24 weeks of treatment with eltrombopag will be authorised under this criterion

Authority required
Continuing therapy or re-initiation after a break in therapy
First period of PBS-subsidised continuing treatment or re-initiation of interrupted PBS-subsidised treatment, as the sole PBS-subsidised thrombopoietin receptor agonist (TRA), of severe thrombocytopenia in an adult patient with chronic immune (idiopathic) thrombocytopenic purpura (ITP) who has displayed a sustained platelet response to treatment with eltrombopag during the initial period of PBS-subsidised treatment.
For the purposes of this restriction, a sustained platelet response is defined as:
(a) use of rescue medication (corticosteroids or immunoglobulins) on no more than one occasion during the initial period of PBS-subsidised eltrombopag,
AND either of the following:
(b) a platelet count greater than or equal to 50,000 million per L on at least four (4) occasions, each at least one week apart;
OR
(c) a platelet count greater than 30,000 million per L and which is double the baseline (pre-treatment) platelet count on at least four (4) occasions, each at least one week apart.
Applications for the first period of continuing PBS-subsidised treatment or re-initiation of interrupted treatment must be made in writing and must include:

(1) a completed authority prescription form, and
(2) a completed Idiopathic Thrombocytopenic Purpura Continuing PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)], and
(3) copies of the platelet count pathology reports (unless previously provided for patients re-initiating therapy).

The most recent platelet count must be no more than one month old at the time of application.

A maximum of 24 weeks of treatment with eltrombopag will be authorised under this criterion. Where fewer than 5 repeats are initially requested with the authority prescription, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be made by telephone.

**Authority required**

Second and subsequent applications for continuing therapy

Continuing treatment, as the sole PBS-subsidised thrombopoietin receptor agonist (TRA), of severe thrombocytopenia in an adult patient with chronic immune (idiopathic) thrombocytopenic purpura (ITP) who has previously received PBS-subsidised therapy with eltrombopag and who continues to display a response to treatment with eltrombopag.

For the purposes of this restriction, a continuing response to treatment with eltrombopag is defined as:

(a) use of rescue medication (corticosteroids or immunoglobulins) on no more than one occasion during the most recent 24 week period of PBS-subsidised treatment with eltrombopag,

AND either of the following:

(b) a platelet count greater than or equal to 50,000 million per L
 OR
(c) a platelet count greater than 30,000 million per L and which is double the baseline platelet count.

Platelet counts must be no more than 1 month old at the time of application.

Authority applications for second and subsequent periods of continuing therapy may be made by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Note**

Eltrombopag is not PBS-subsidised as an alternative to splenectomy.

Any queries concerning the arrangements to prescribe eltrombopag may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authority to prescribe eltrombopag should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Eltrombopag is not PBS-subsidised as an alternative to splenectomy.

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.

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### eltrombopag 50 mg tablet, 28

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#### ROMIPLOSTIM

**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-subsidised treatment, 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

HOBART TAS 7001

Further prescribing information is on the Medicare Australia website at www.medicareaustralia.gov.au.

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.

Special Pricing Arrangements apply.
### Darbepoetin Alfa

**Darbepoetin Alfa 100 microgram/0.5 mL injection, 1 x 0.5 mL syringe**

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**Darbepoetin Alfa 100 microgram/0.5 mL injection, 4 x 0.5 mL syringes**

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**Darbepoetin Alfa 150 microgram/0.3 mL injection, 1 x 0.3 mL syringe**

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**Darbepoetin Alfa 150 microgram/0.3 mL injection, 4 x 0.3 mL syringes**

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**Darbepoetin Alfa 20 microgram/0.5 mL injection, 1 x 0.5 mL syringe**

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**Darbepoetin Alfa 20 microgram/0.5 mL injection, 4 x 0.5 mL syringes**

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**Darbepoetin Alfa 30 microgram/0.3 mL injection, 4 x 0.3 mL syringes**

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**Darbepoetin Alfa 40 microgram/0.4 mL injection, 1 x 0.4 mL syringe**

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**Darbepoetin Alfa 40 microgram/0.4 mL injection, 4 x 0.4 mL syringes**

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**Darbepoetin Alfa 50 microgram/0.5 mL injection, 4 x 0.5 mL syringes**

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**Darbepoetin Alfa 60 microgram/0.3 mL injection, 1 x 0.3 mL syringe**

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**Darbepoetin Alfa 60 microgram/0.3 mL injection, 4 x 0.3 mL syringes**

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**Darbepoetin Alfa 80 microgram/0.4 mL injection, 1 x 0.4 mL syringe**

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**Darbepoetin Alfa 80 microgram/0.4 mL injection, 4 x 0.4 mL syringes**

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### Epoetin Alfa

**Epoetin Alfa 10 000 international units/mL injection, 6 x 1 mL syringes**

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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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**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.

---

### epoetin lambda 10 000 international units/mL injection, 6 x 1 mL syringes

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<tr>
<th>Max Qty</th>
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### epoetin lambda 1000 international units/0.5 mL injection, 6 x 0.5 mL syringes

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### epoetin lambda 2000 international units/mL injection, 6 x 1 mL syringes

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### epoetin lambda 3000 international units/0.3 mL injection, 6 x 0.3 mL syringes

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### epoetin lambda 4000 international units/0.4 mL injection, 6 x 0.4 mL syringes

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### epoetin lambda 6000 international units/0.6 mL injection, 6 x 0.6 mL syringes

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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.

### methoxy polyethylene glycol-eopoetin beta 100 microgram/0.3 mL injection, 1 x 0.3 mL syringe

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### methoxy polyethylene glycol-eopoetin beta 120 microgram/0.3 mL injection, 1 x 0.3 mL syringe

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### methoxy polyethylene glycol-eopoetin beta 200 microgram/0.3 mL injection, 1 x 0.3 mL syringe

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### methoxy polyethylene glycol-eopoetin beta 30 microgram/0.3 mL injection, 1 x 0.3 mL syringe

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### methoxy polyethylene glycol-eopoetin beta 360 microgram/0.6 mL injection, 1 x 0.6 mL syringe

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CARDIOVASCULAR SYSTEM

**methoxy polyethylene glycol-eopoetin beta 50 microgram/0.3 mL injection, 1 x 0.3 mL syringe**

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**methoxy polyethylene glycol-eopoetin beta 75 microgram/0.3 mL injection, 1 x 0.3 mL syringe**

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### CARDIOVASCULAR SYSTEM

### ANTIHYPERTENSIVES

#### OTHER ANTIHYPERTENSIVES

**Antihypertensives for pulmonary arterial hypertension**

#### AMBRISENTAN

**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.

**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.

**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, **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 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.

**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 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 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.

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 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 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 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 for 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.
**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. 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. ambrisentan 10 mg tablet, 30
9649W Max Qty Packs No. of Rpts Premium $ DPMQ $ Brand Name and Manufacturer
1 .. .. 2923.23 Volibris [GK]
ambrisentan 5 mg tablet, 30
9648T Max Qty Packs No. of Rpts Premium $ DPMQ $ Brand Name and Manufacturer
1 .. .. 2923.23 Volibris [GK]

**BOSENTAN**

**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.

**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:

1. 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.

Appraisals 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.

**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
CARDIOVASCULAR SYSTEM

(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.

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 heritable 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 heritable 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.

Authorities 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. Authorities 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 prescribed 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.

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.

**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) – balance of supply

**Clinical criteria:**

Patient must have received insufficient therapy with this agent under the Initial 1 (new patients) restriction to complete a maximum of six months of treatment; OR

Patient must have received insufficient therapy with this agent under the Initial 2 (new patients) restriction to complete a maximum of six months of treatment; OR

Patient must have received insufficient therapy with this agent under the Initial 3 (change or re-commencement of therapy for all patients) restriction to complete a maximum of six months of treatment; OR

Patient must have received insufficient therapy with this agent under the Continuing treatment (all patients) restriction to complete a maximum of six months of treatment. **AND**

The treatment must be the sole PBS-subsidised PAH agent for this condition, **AND**

The treatment must provide no more than the balance of up to six months treatment available under the above restrictions.

**Note**

Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authorisation under this criterion should be forwarded to:

Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826

HOBART TAS 7001

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Continuing treatment (all patients)

**Clinical criteria:**

Patient must have received approval for initial PBS-subsidised treatment with this agent, **AND**
Patient must have been assessed by a physician from a designated hospital to have achieved a response to their most recent course of treatment with this agent, **AND**

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

1. A completed authority prescription form; and
2. A completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
   (i) RHC composite assessment; and
   (ii) ECHO composite assessment; and
   (iii) 6 Minute Walk Test (6MWT).

Test requirements to establish response to treatment for continuation of treatment are as follows:

- The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:
  1. RHC plus ECHO composite assessments plus 6MWT;
  2. RHC plus ECHO composite assessments;
  3. RHC composite assessment plus 6MWT;
  4. ECHO composite assessment plus 6MWT;
  5. RHC composite assessment only;
  6. ECHO composite assessment only.

The results of the same tests as conducted at baseline should be provided with each written continuing treatment application (i.e., every 6 months), except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application.

The test results provided with the application for continuing treatment must be no more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

The assessment of the patient’s response to the first and subsequent 6 month courses of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Applications for continuing treatment with a PAH agent should be made prior to the completion of the 6 month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term ‘PAH agents’ refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

**Note**

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826

HOBART TAS 7001

Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

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**BOSENTAN**

**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.

**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 pulmonary artery pressure of 25 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, 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.

- 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.

**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:
   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.

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.

**Authority required**

Pulmonary arterial hypertension (PAH)

**Treatment Phase: Initial 3 (change or re-commencement of therapy for all patients)**

**Clinical criteria:**

- Patients must have idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or heritable 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 have demonstrated a response to their most recent course of PBS-subsidised treatment with this agent; OR
- Patients must have idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or heritable 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, where 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-quality 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.

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.

**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.

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
CARDIOVASCULAR SYSTEM

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

Prescribing information (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.

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.

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:
(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:
CARDIOVASCULAR SYSTEM

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. 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.

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 (change or re-commencement of therapy for all patients)

**Clinical criteria:**

Patient must have idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease and must wish to re-commence PBS-subsidised therapy with this agent after a break in therapy and must have demonstrated a response to their most recent course of PBS-subsidised treatment with this agent; OR

Patient must have WHO Functional Class IV idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease and must have received prior treatment with a PBS-subsidised PAH agent other than this agent; OR

Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease and must have failed to respond to a prior PBS-subsidised PAH agent, **AND**

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and
(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form; and
(3) the results of the patient’s response to treatment with their last course of PBS-subsidised PAH agent; and
(4) for WHO Functional Class III patients, where this is the first application for this agent, assessment details of the PBS-subsidised PAH agent they have failed to respond to.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats may be requested.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term ‘PAH agents’ refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Swapping between PAH agents:
Patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment with 1 of these 7 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. New baselines may be submitted where the patient has failed to respond to their current treatment.

Eligible patients may only swap between PAH agents if they have not failed prior PBS-subsidised treatment with that agent. For eligible patients, applications to swap between the 7 PAH agents must be made under the relevant initial treatment restriction. Patients should be assessed for response to the treatment they are ceasing at the time the application to swap therapy is being made. Patients who fail to demonstrate a response or for whom no assessment results are submitted with the application to swap therapy may not re-commence PBS-subsidised treatment with the drug they are ceasing.

**Note**
Applications for patients who wish to swap to an alternate PAH agent should be accompanied by the previously approved authority prescription, or remaining repeats, for the treatment the patient is ceasing.

**Authority required**
Pulmonary arterial hypertension (PAH)

**Clinical criteria:**
- Patient must have received insufficient therapy with this agent under the Initial 1 (new patients) restriction to complete a maximum of six months of treatment; OR
- Patient must have received insufficient therapy with this agent under the Initial 2 (change or re-commencement of therapy for all patients) restriction to complete a maximum of six months of treatment; OR
- Patient must have received insufficient therapy with this agent under the Continuing treatment (all patients) restriction to complete a maximum of six months of treatment, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition, **AND**
- The treatment must provide no more than the balance of up to six months treatment available under the above restrictions.

**Note**
Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authorisation under this criterion should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826

**HOBART TAS 7001**

**Authority required**
Pulmonary arterial hypertension (PAH)

**Clinical criteria:**
- Patient must have received approval for initial PBS-subsidised treatment with this agent, **AND**
- Patient must have been assessed by a physician from a designated hospital to have achieved a response to their most recent course of treatment with this agent, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:
- (1) a completed authority prescription form; and
- (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
  - (i) RHC composite assessment; and
  - (ii) ECHO composite assessment; and
  - (iii) 6 Minute Walk Test (6MWT).

Test requirements to establish response to treatment for continuation of treatment are as follows:
- The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:
  - (1) RHC plus ECHO composite assessments plus 6MWT;
  - (2) RHC plus ECHO composite assessments;
  - (3) RHC composite assessment plus 6MWT;
  - (4) ECHO composite assessment plus 6MWT;
  - (5) RHC composite assessment only;
  - (6) ECHO composite assessment only.

The results of the same tests as conducted at baseline should be provided with each written continuing treatment application (i.e., every 6 months), except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application.
The test results provided with the application for continuing treatment must be no more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

The assessment of the patient’s response to the first and subsequent 6 month courses of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Applications for continuing treatment with a PAH agent should be made prior to the completion of the 6 month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term ‘PAH agents’ refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Note

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of 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.

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.

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.

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**EPOPROSTENOL SODIUM Powder for I.V. infusion 1.5 mg (base) infusion administration set, 1**

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**EPOPROSTENOL SODIUM Powder for I.V. infusion 500 micrograms (base) infusion administration set, 1**

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**epoprostenol 1.5 mg injection, 1 x 1.5 mg vial**

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**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**
Schedule of Pharmaceutical Benefits

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 authorit 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.

**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**
CARDIOVASCULAR SYSTEM

Patient must have WHO Functional Class III drug-induced PAH and a mean right atrial pressure greater than 8 mmHg, as measured by right heart catheterisation (RHC); OR
Patient must have WHO Functional Class III drug-induced PAH with right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds; OR
Patient must have WHO Functional Class IV idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH; OR
Patient must have WHO Functional Class IV pulmonary arterial hypertension secondary to connective tissue disease; OR
Patient must have WHO Functional Class IV drug-induced PAH, **AND**

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and
(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

(i) RHC composite assessment; and
(ii) ECHO composite assessment; and
(iii) 6 Minute Walk Test (6MWT); and
(3) a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditable pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger’s physiology) are defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or
(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient’s baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments;
(2) RHC composite assessment plus 6MWT;
(3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

(1) ECHO composite assessment plus 6MWT;
(2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats may be requested.

The term ‘PAH agents’ refers to bosentan monohydrate, iloprost trentamol, 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.

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 3 (change or re-commencement of therapy for all patients)

**Clinical criteria:**

Patient must have idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease or drug-induced PAH and must wish to re-commence PBS-subsidised therapy with this agent after a break in therapy and must have demonstrated a response to their most recent course of PBS-subsidised treatment with this agent; OR

Patient must have WHO Functional Class IV idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease and must have received prior treatment with a PBS-subsidised PAH agent other than this agent; OR

Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease and must have failed to respond to a prior PBS-subsidised PAH agent, **AND**

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and
(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form; and
(3) the results of the patient's response to treatment with their last course of PBS-subsidised PAH agent; and
(4) for WHO Functional Class III patients, where this is the first application for this agent, assessment details of the PBS-subsidised PAH agent they have failed to respond to.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats may be requested.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalfil, 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 submitted. 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.

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 or Initial 2 (new patients) or Initial 3 (change or re-commencement of therapy for all patients) or Continuing treatment (all patients) – balance of supply

**Clinical criteria:**

Patient must have received insufficient therapy with this agent under the Initial 1 (new patients) restriction to complete a maximum of six months of treatment; OR

Patient must have received insufficient therapy with this agent under the Initial 2 (new patients) restriction to complete a maximum of six months of treatment; OR

Patient must have received insufficient therapy with this agent under the Initial 3 (change or re-commencement of therapy for all patients) restriction to complete a maximum of six months of treatment; OR

Patient must have received insufficient therapy with this agent under the Continuing treatment (all patients) restriction to complete a maximum of six months of treatment, **AND**

The treatment must be the sole PBS-subsidised PAH agent for this condition, **AND**

The treatment must provide no more than the balance of up to six months treatment available under the above restrictions.

**Note**

Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authorisation under this criterion should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Continuing treatment (all patients)

**Clinical criteria:**
Patient must have received approval for initial PBS-subsidised treatment with this agent, AND
Patient must have been assessed by a physician from a designated hospital to have achieved a response to their most recent course of treatment with this agent, AND
The treatment must be the sole PBS-subsidised PAH agent for this condition.
Applications for authorisation must be in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
(i) RHC composite assessment; and
(ii) ECHO composite assessment; and
(iii) 6 Minute Walk Test (6MWT).
Test requirements to establish response to treatment for continuation of treatment are as follows:
The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:
(1) RHC plus ECHO composite assessments plus 6MWT;
(2) RHC plus ECHO composite assessments;
(3) RHC composite assessment plus 6MWT;
(4) ECHO composite assessment plus 6MWT;
(5) RHC composite assessment only;
(6) ECHO composite assessment only.
The results of the same tests as conducted at baseline should be provided with each written continuing treatment application (i.e., every 6 months), except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application.
The test results provided with the application for continuing treatment must be no more than 2 months old at the time of application.
Response to a PAH agent is defined as follows:
For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital. For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital. For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital. For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.
The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.
A maximum of 5 repeats will be authorised.
The assessment of the patient’s response to the first and subsequent 6 month courses of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated. Applications for continuing treatment with a PAH agent should be made prior to the completion of the 6 month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician.
Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.
The term ‘PAH agents’ refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.
PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

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

**iloprost**

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**Ilprostil 20 microgram/2 mL inhalation: solution, 30 x 2 mL ampoules**
MACITENTAN

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.

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 when 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.

**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:
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.

**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 heritable 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 heritable 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.

**Authority required**

Pulmonary arterial hypertension (PAH)

**Treatment Phase:** Initial 1 or Initial 2 (new patients) or Initial 3 (change or re-commencement of therapy for all patients) or Continuing treatment (all patients) – balance of supply

**Clinical criteria:**

Patient must have received insufficient therapy with this agent under the Initial 1 (new patients) restriction to complete a maximum of six months of treatment; OR

Patient must have received insufficient therapy with this agent under the Initial 2 (new patients) restriction to complete a maximum of six months of treatment; OR

Patient must have received insufficient therapy with this agent under the Initial 3 (change or re-commencement of therapy for all patients) restriction to complete a maximum of six months of treatment; OR

Patient must have received insufficient therapy with this agent under the Continuing treatment (all patients) restriction to complete a maximum of six months of treatment, **AND**
The treatment must be the sole PBS-subsidised PAH agent for this condition, AND
The treatment must provide no more than the balance of up to six months treatment available under the above restrictions.

**Note**
Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Written applications for authorisation under this criterion should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826

HOBART TAS 7001

**Authority required**
Pulmonary arterial hypertension (PAH)
Treatment Phase: Continuing treatment (all patients)

**Clinical criteria:**
Patient must have received approval for initial PBS-subsidised treatment with this agent, AND
Patient must have been assessed by a physician from a designated hospital to have achieved a response to their most recent course of treatment with this agent, AND
The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
(i) RHC composite assessment; and
(ii) ECHO composite assessment; and
(iii) 6 Minute Walk Test (6MWT).

Test requirements to establish response to treatment for continuation of treatment are as follows:
The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:
(1) RHC plus ECHO composite assessments plus 6MWT;
(2) RHC plus ECHO composite assessments;
(3) RHC composite assessment plus 6MWT;
(4) ECHO composite assessment plus 6MWT;
(5) RHC composite assessment only;
(6) ECHO composite assessment only.

The results of the same tests as conducted at baseline should be provided with each written continuing treatment application (i.e., every 6 months), except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application.
The test results provided with the application for continuing treatment must be no more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:
For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.
For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.
For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.
For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.
The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.
A maximum of 5 repeats will be authorised.
The assessment of the patient’s response to the first and subsequent 6 month courses of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.
Applications for continuing treatment with a PAH agent should be made prior to the completion of the 6 month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician.
Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.
The term ‘PAH agents’ refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.
PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

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

HOBART TAS 7001
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
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.

**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 WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH, and a mean right atrial pressure of greater than 8 mmHg, as measured by right heart catheterisation (RHC); OR
Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH, with right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds; OR
Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease and a mean right atrial pressure greater than 8 mmHg, as measured by RHC; OR
Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease with right ventricular function assessed by ECHO where a RHC cannot be performed on clinical grounds, AND
The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
(i) RHC composite assessment; and
(ii) ECHO composite assessment; and
(iii) 6 Minute Walk Test (6MWT); and
(3) a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditable pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:
(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or
(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:
The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:
(1) RHC plus ECHO composite assessments;
(2) RHC composite assessment plus 6MWT;
(3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:
(1) ECHO composite assessment plus 6MWT;
(2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.
The test results provided must not be more than 2 months old at the time of application. The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information. A maximum of 5 repeats may be requested.

The term ‘PAH agents’ refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent. PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

### Authority required

**Pulmonary arterial hypertension (PAH)**

**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, 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.

**Authority required**

**Pulmonary arterial hypertension (PAH)**

**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 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.
Cardiovascular System

Patient must have received insufficient therapy with this agent under the Initial 1 (new patients) restriction to complete a maximum of six months of treatment; OR
Patient must have received insufficient therapy with this agent under the Initial 2 (new patients) restriction to complete a maximum of six months of treatment; OR
Patient must have received insufficient therapy with this agent under the Initial 3 (change or re-commencement of therapy for all patients) restriction to complete a maximum of six months of treatment; OR
Patient must have received insufficient therapy with this agent under the Continuing treatment (all patients) restriction to complete a maximum of six months of treatment, AND
The treatment must be the sole PBS-subsidised PAH agent for this condition, AND
The treatment must provide no more than the balance of up to six months treatment available under the above restrictions.

Note
Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written applications for authorisation under this criterion should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Authority required
Pulmonary arterial hypertension (PAH)
Treatment Phase: Continuing treatment (all patients)
Clinical criteria:
Patient must have received approval for initial PBS-subsidised treatment with this agent, AND
Patient must have been assessed by a physician from a designated hospital to have achieved a response to their most recent course of treatment with this agent, AND
The treatment must be the sole PBS-subsidised PAH agent for this condition.
Applications for authorisation must be in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
(i) RHC composite assessment; and
(ii) ECHO composite assessment; and
(iii) 6 Minute Walk Test (6MWT).
Test requirements to establish response to treatment for continuation of treatment are as follows:
The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:
(1) RHC plus ECHO composite assessments plus 6MWT;
(2) RHC plus ECHO composite assessments;
(3) RHC composite assessment plus 6MWT;
(4) ECHO composite assessment plus 6MWT;
(5) RHC composite assessment only;
(6) ECHO composite assessment only.
The results of the same tests as conducted at baseline should be provided with each written continuing treatment application (i.e., every 6 months), except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application.
The test results provided with the application for continuing treatment must be no more than 2 months old at the time of application.
Response to a PAH agent is defined as follows:
For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.
For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.
For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.
For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.
The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.
A maximum of 5 repeats will be authorised.
The assessment of the patient's response to the first and subsequent 6 month courses of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.
Applications for continuing treatment with a PAH agent should be made prior to the completion of the 6 month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician.
Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

**Note**

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826

HOBART TAS 7001

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:

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.

**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:
   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.

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.

**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.

Authority required
Pulmonary arterial hypertension (PAH)
Treatment Phase: Initial 1 or Initial 2 (new patients) or Initial 3 (change or re-commencement of therapy for all patients) or Continuing treatment (all patients) – balance of supply
Clinical criteria:
Patient must have received insufficient therapy with this agent under the Initial 1 (new patients) restriction to complete a maximum of six months of treatment; OR
Patient must have received insufficient therapy with this agent under the Initial 2 (new patients) restriction to complete a maximum of six months of treatment; OR
Patient must have received insufficient therapy with this agent under the Initial 3 (change or re-commencement of therapy for all patients) restriction to complete a maximum of six months of treatment; OR
Patient must have received insufficient therapy with this agent under the Continuing treatment (all patients) restriction to complete a maximum of six months of treatment, AND
The treatment must be the sole PBS-subsidised PAH agent for this condition, AND
The treatment must provide no more than the balance of up to six months treatment available under the above restrictions.

Note
Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written applications for authorisation under this criterion should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Authority required
Pulmonary arterial hypertension (PAH)
Treatment Phase: Continuing treatment (all patients)
Clinical criteria:
Patient must have received approval for initial PBS-subsidised treatment with this agent, AND
Patient must have been assessed by a physician from a designated hospital to have achieved a response to their most recent course of treatment with this agent, AND
The treatment must be the sole PBS-subsidised PAH agent for this condition.
Applications for authorisation must be in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
(i) RHC composite assessment; and
(ii) ECHO composite assessment; and
(iii) 6 Minute Walk Test (6MWT).
Test requirements to establish response to treatment for continuation of treatment are as follows:
The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:
(1) RHC plus ECHO composite assessments plus 6MWT;
(2) RHC plus ECHO composite assessments;
(3) RHC composite assessment plus 6MWT;
(4) ECHO composite assessment plus 6MWT;
(5) RHC composite assessment only;
(6) ECHO composite assessment only.
The results of the same tests as conducted at baseline should be provided with each written continuing treatment application (i.e., every 6 months), except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application.
The test results provided with the application for continuing treatment must be no more than 2 months old at the time of application.
Response to a PAH agent is defined as follows:
For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.
For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.
For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.
For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital. The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information. A maximum of 5 repeats will be authorised.

The assessment of the patient’s response to the first and subsequent 6 month courses of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated. Applications for continuing treatment with a PAH agent should be made prior to the completion of the 6 month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent. The term ‘PAH agents’ refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

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

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

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826

HOBART TAS 7001
Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>Adcirca [LY]</td>
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</table>

**Lanreotide**

**Authority required**

**Acromegaly**

**Clinical criteria:**

- The condition must be active, AND
- Patient must have persistent elevation of mean growth hormone levels of greater than 2.5 micrograms per litre, 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.

**Lanreotide 30 mg injection: modified release [1 x 30 mg vial] (&) inert substance diluent [1 x 2 mL ampoule], 1 pack**

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>Somatuline LA [IS]</td>
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**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.

**LANREOTIDE**

### Octreotide 120 mg injection, 1 syringe

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### Octreotide 60 mg injection, 1 syringe

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### Octreotide 90 mg injection, 1 syringe

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### OCTREOTIDE

**Authority required**
Active acromegaly in a patient with persistent elevation of mean growth hormone levels of greater than 2.5 micrograms per litre AND
(a) after failure of other therapy including dopamine agonists; or
(b) as interim treatment while awaiting the effects of radiotherapy and where treatment with dopamine agonists has failed; or
(c) if the patient is unfit for or unwilling to undergo surgery and where radiotherapy is contraindicated.
In a patient treated with radiotherapy, treatment must cease if there is biochemical evidence of remission (normal IGF1) after octreotide has been withdrawn for at least 4 weeks. Octreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission.
Treatment must cease if IGF1 is not lower after 3 months treatment at a dose of 100 micrograms 3 times daily

**Authority required**
Functional carcinoid tumour or vasoactive intestinal peptide secreting tumour (VIPoma) causing intractable symptoms. The patient must have experienced on average over 1 week, 3 or more episodes per day of diarrhoea and/or flushing, which persisted despite the use of anti-histamines, anti-serotonin agents and anti-diarrhoea agents, and surgery or antineoplastic therapy must have failed or be inappropriate.
Treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 2 months' therapy. Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.

**Octreotide 100 microgram/mL injection, 5 x 1 mL ampoules**

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<td>Octreotide MaxRx [GQ]</td>
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**Octreotide 50 microgram/mL injection, 5 x 1 mL ampoules**

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**Octreotide 500 microgram/mL injection, 5 x 1 mL ampoules**

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<td>Sandostatin 0.5 [NV]</td>
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</table>
OCTREOTIDE

Authority required

Acromegaly

Clinical criteria:
The condition must be controlled with octreotide immediate release injections, AND
The treatment must cease 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.

octreotide 10 mg injection: modified release [1 x 10 mg vial] (&) inert substance diluent [1 x 2.5 mL syringe], 1 pack

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octreotide 20 mg injection: modified release [1 x 20 mg vial] (&) inert substance diluent [1 x 2.5 mL syringe], 1 pack

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octreotide 30 mg injection: modified release [1 x 30 mg vial] (&) inert substance diluent [1 x 2.5 mL syringe], 1 pack

<table>
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CALCIUM HOMEOSTASIS

ANTI-PARATHYROID AGENTS

Other anti-parathyroid agents

CINACALCET

Authority required

Management, including initiation and stabilisation, by a nephrologist, of a patient with chronic kidney disease on dialysis who has sustained secondary hyperparathyroidism with iPTH of at least 50 pmol per L, not responding to conventional therapy

Authority required

Management, including initiation and stabilisation, by a nephrologist, of a patient with chronic kidney disease on dialysis who has sustained secondary hyperparathyroidism with iPTH of at least 15 pmol per L AND 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. Special Pricing Arrangements apply.

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
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<tr>
<td>Sensipar [AN]</td>
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</table>

## ANTIBACTERIALS FOR SYSTEMIC USE

### MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS

**Macrolides**

#### AZITHROMYCIN

**Authority required**

Prophylaxis against Mycobacterium avium complex infections in HIV-positive patients with CD4 cell counts of less than 75 per cubic millimetre

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<th><strong>azithromycin 600 mg tablet, 8</strong></th>
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<td>2 5 .. *139.94 Zithromax [PF]</td>
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#### CLARITHROMYCIN

**Authority required**

Treatment of Mycobacterium avium complex infections

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## ANTIVIRALS FOR SYSTEMIC USE

### DIRECT ACTING ANTIVIRALS

**Nucleosides and nucleotides excl. reverse transcriptase inhibitors**

#### GANCICLOVIR

**Authority required**

Cytomegalovirus retinitis in severely immunocompromised patients

<table>
<thead>
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<th><strong>GANCICLOVIR</strong></th>
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<tbody>
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<td>4 5 .. *880.00 Mycobutin [PF]</td>
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</table>
Prophylaxis of cytomegalovirus disease in bone marrow transplant patients at risk of cytomegalovirus disease

**Authority required**

Prophylaxis of cytomegalovirus disease in solid organ transplant patients at risk of cytomegalovirus disease

ganciclovir 500 mg injection, 5 x 500 mg vials

<table>
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<tr>
<th>Max Qty</th>
<th>Packs</th>
<th>No. of Rpts</th>
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**VALACICLOVIR**

**Authority required**

Prophylaxis of cytomegalovirus (CMV) infection and disease following renal transplantation in patients at risk of CMV disease

valaciclovir 500 mg tablet, 100

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<th>Max Qty</th>
<th>Packs</th>
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**VALGANCICLOVIR**

**Authority required**

Cytomegalovirus retinitis in patients with acquired immunodeficiency syndrome

**Authority required**

Prophylaxis of cytomegalovirus infection and disease in solid organ transplant patients at risk of cytomegalovirus disease

valganciclovir 450 mg tablet, 60

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valganciclovir 50 mg/mL oral liquid: powder for, 100 mL

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**Phosphonic acid derivatives**

**FOSCARNET**

**Authority required**

Treatment of cytomegalovirus retinitis in patients with AIDS

**Authority required**

Treatment of aciclovir-resistant herpes simplex virus infection in immunocompromised patients with HIV infection

FOSCARNET SODIUM I.V. infusion 24 mg per mL, 250 mL bottle, 6

<table>
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**Protease inhibitors**

**ATAZANAVIR**

**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.

atazanavir 150 mg capsule, 60

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atazanavir 200 mg capsule, 60

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</table>
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 relapsers 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.
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 who were partial responders or relapsers to the prior course of interferon based therapy, a maximum of 7 repeats may be prescribed.
For patients without hepatic cirrhosis who were null responders to the prior course of interferon based therapy, a maximum of 10 repeats may be prescribed.
For patients with hepatic cirrhosis, a maximum of 10 repeats may be prescribed.

Authority required

Chronic genotype 1 hepatitis C infection

Clinical criteria:
Patient must have compensated liver disease, AND
Patient must not have received prior interferon alfa or peginterferon alfa treatment for hepatitis C, AND
The treatment must be in combination with peginterferon alfa and ribavirin, AND
The treatment must be limited to a maximum duration of 24 weeks in patients without hepatic cirrhosis; OR
The treatment must be limited to a maximum duration of 44 weeks in patients with hepatic cirrhosis, AND
The treatment must cease after the first 20 weeks of boceprevir treatment if plasma HCV RNA is detectable by an HCV RNA qualitative assay at treatment week 24.

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.
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.

**Boceprevir 200 mg capsule, 336 capsules**

<table>
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**DARUNAVIR**

**Authority required**

**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.

**darunavir 800 mg tablet, 30**

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**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.**

**darunavir 150 mg tablet, 240**

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**darunavir 600 mg tablet, 60**

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**FOSAMPRENAVIR**

**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.

**fosamprenavir 50 mg/mL oral liquid, 225 mL**

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**fosamprenavir 700 mg tablet, 60**

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**INDINAVIR**

**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.

indinavir 400 mg capsule, 180

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RITONAVIR

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.

Ritonavir 100 mg tablet, 30

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Ritonavir 600 mg/7.5 mL oral liquid, 90 mL

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SAQUINAVIR

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.

Saquinavir 500 mg tablet, 120

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SIMEPREVIR

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 12 weeks, AND
The treatment must cease if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is 25 IU/mL or greater.
Population criteria:
Patient must be aged 18 years or older, AND
Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

Treatment criteria:
Must be treated in an accredited treatment centre.
Evidence of chronic genotype 1 hepatitis C infection (repeatedly anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.
Patients who have received prior treatment with an NS3/4A protease inhibitor are not eligible to receive PBS-subsidised simeprevir, except where the patient has developed an intolerance to the other NS3/4A protease inhibitor of a severity necessitating permanent treatment withdrawal. Details of the intolerance must be documented in the patient's medical records.

Authority required
Chronic genotype 1 hepatitis C infection

Clinical criteria:
Patient must have compensated liver disease, AND
Patient must have received prior treatment with interferon alfa or peginterferon alfa for hepatitis C, AND
The treatment must be in combination with peginterferon alfa and ribavirin, AND
The treatment must be limited to a maximum duration of 12 weeks, AND
The treatment must cease if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is 25 IU/mL or greater.

Population criteria:
Patient must be 18 years or older, AND
Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

Treatment criteria:
Must be treated in an accredited treatment centre.
Evidence of chronic genotype 1 hepatitis C infection (repeatedly anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.
Patients who have received prior treatment with an NS3/4A protease inhibitor are not eligible to receive PBS-subsidised simeprevir, except where the patient has developed an intolerance to the other NS3/4A protease inhibitor of a severity necessitating permanent treatment withdrawal. Details of the intolerance must be documented in the patient's medical records.

Note
No increase in the maximum quantity or number of units may be authorised.
No increase in the maximum number of repeats may be authorised.
Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:
(a) a nurse educator/counsellor for patients; and
(b) 24-hour access by patients to medical advice; and
(c) an established liver clinic.

simeprevir sodium 150 mg capsule, 7

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<td>*14912.50</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, AND
The treatment must cease if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is greater than 1000 IU/mL.

**Population criteria:**
Patient must be 18 years or older, AND
Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

**Treatment criteria:**
Must be treated in an accredited treatment centre.
Evidence of chronic genotype 1 hepatitis C infection (repeatedly anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.
Patients who have received prior treatment with an NS3/4A protease inhibitor are not eligible to receive PBS-subsidised telaprevir, except where the patient has developed an intolerance to the other NS3/4A protease inhibitor of a severity necessitating permanent treatment withdrawal. Details of the intolerance must be documented in the patient's medical records.

**Note**
No increase in the maximum quantity or number of units may be authorised.
No increase in the maximum number of repeats may be authorised.
Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:
(a) a nurse educator/counsellor for patients; and
(b) 24-hour access by patients to medical advice; and
(c) an established liver clinic.

telaprevir 375 mg tablet, 42

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**TIPRANAVIR**

**Authority required**
Treatment of HIV infection, in addition to optimised background therapy in combination with other antiretroviral agents, and co-administered with 200 mg ritonavir twice daily in an antiretroviral experienced patient who, after each of at least three different antiretroviral regimens that have included one drug from at least 3 different antiretroviral classes, has experienced virological failure or clinical failure or genotypic resistance.
Virological failure is defined as a viral load greater than 400 copies per mL on two consecutive occasions, while clinical failure is linked to emerging signs and symptoms of progressing HIV infection or treatment-limiting toxicity.

**Note**
Special Pricing Arrangements apply.

tipranavir 250 mg capsule, 120

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**Nucleoside and nucleotide reverse transcriptase inhibitors**

**ABACAVIR**

**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.
### Antiinfectives for Systemic Use

#### Abacavir 20 mg/mL Oral Liquid, 240 mL

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#### Abacavir 300 mg Tablet, 60

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<td>*593.32</td>
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### 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:

(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 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.

#### Adefovir Dipivoxil 10 mg Tablet, 30

<table>
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### Didanosine

**Authority required**

HIV infection

**Clinical criteria:**

Patient must be antiretroviral treatment naïve, **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.

#### Didanosine 125 mg Capsule: Enteric, 30

<table>
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#### Didanosine 200 mg Capsule: Enteric, 30

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#### Didanosine 250 mg Capsule: Enteric, 30

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#### Didanosine 400 mg Capsule: Enteric, 30

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</tbody>
</table>

### Emtricitabine

**Authority required**

HIV infection

**Clinical criteria:**

Patient must be antiretroviral treatment naïve, **AND**

The treatment must be in combination with other antiretroviral agents.
ANTIINFECTIVES FOR SYSTEMIC USE

**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 200 mg capsule, 30**

<table>
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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

**Authority required**
Chronic hepatitis B in a patient with cirrhosis who has detectable HBV DNA.
Persons with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy.

**Note**
PBS-subsidised entecavir monohydrate must be used as monotherapy.

**Entecavir monohydrate 500 microgram tablet, 30**

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- **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.

**Entecavir monohydrate 1 mg tablet, 30**

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- **LAMIVUDINE**

**Authority required**
HIV infection
Treatment Phase: Initial

**Clinical criteria:**
Patient must be antiretroviral treatment naive, **AND**
The treatment must be in combination with other antiretroviral agents.

**Authority required**
HIV infection
Treatment Phase: Continuing

**Clinical criteria:**
Patient must have previously received PBS-subsidised therapy for HIV infection, **AND**
The treatment must be in combination with other antiretroviral agents.
ANTIINFECTIVES FOR SYSTEMIC USE

lamivudine 10 mg/mL oral liquid, 240 mL
6194B
Max Qty Packs No. of Rpts Premium $ DPMQ $ Brand Name and Manufacturer
8 5 .. *472.52 3TC [VI]

lamivudine 150 mg tablet, 60
6193Y
Max Qty Packs No. of Rpts Premium $ DPMQ $ Brand Name and Manufacturer
2 5 .. *325.70 * 3TC [VI] * Lamivudine RBX [RA]

lamivudine 300 mg tablet, 30
643SQ
Max Qty Packs No. of Rpts Premium $ DPMQ $ Brand Name and Manufacturer
2 5 .. *325.70 * 3TC [VI] * Lamivudine Alphapharm [AF]

- LAMIVUDINE

Authority required
Chronic hepatitis B in a patient without cirrhosis who satisfies all of the following criteria:
(1) Elevated HBV DNA levels - greater than 20,000 IU/mL (100,000 copies/mL) if HBeAg positive, or greater than 2,000 IU/mL (10,000 copies/mL) if HBeAg negative - in conjunction with documented chronic hepatitis B infection;
(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

lamivudine 100 mg tablet, 28
6257H
Max Qty Packs No. of Rpts Premium $ DPMQ $ Brand Name and Manufacturer
2 5 .. *175.70 * Zeffix [AS]

lamivudine 5 mg/mL oral liquid, 240 mL
6271C
Max Qty Packs No. of Rpts Premium $ DPMQ $ Brand Name and Manufacturer
5 5 .. *242.06 Zeffix [AS]

- STAVUDINE

Authority required
HIV infection
Treatment Phase: Initial
Clinical criteria:
Patient must be antiretroviral treatment naive, AND
The treatment must be in combination with other antiretroviral agents.

Authority required
HIV infection
Treatment Phase: Continuing
Clinical criteria:
Patient must have previously received PBS-subsidised therapy for HIV infection, AND
The treatment must be in combination with other antiretroviral agents.

stavudine 20 mg capsule, 60
6186N
Max Qty Packs No. of Rpts Premium $ DPMQ $ Brand Name and Manufacturer
2 5 .. *589.16 Zerit [BQ]

stavudine 30 mg capsule, 60
6189R
Max Qty Packs No. of Rpts Premium $ DPMQ $ Brand Name and Manufacturer
2 5 .. *700.82 Zerit [BQ]

stavudine 40 mg capsule, 60
6190T
Max Qty Packs No. of Rpts Premium $ DPMQ $ Brand Name and Manufacturer
2 5 .. *932.16 Zerit [BQ]

- TELBIVUDINE

Authority required
Treatment, as sole PBS-subsidised therapy, in a patient with chronic hepatitis B without cirrhosis who is nucleoside analogue naive and satisfies all of the following criteria:
(1) Elevated HBV DNA levels - greater than 20,000 IU/mL (100,000 copies/mL) if HBeAg positive, or greater than 2,000 IU/mL (10,000 copies/mL) if HBeAg negative - in conjunction with documented hepatitis B infection;
(2) Evidence of chronic liver injury as determined by:
   (a) Confirmed elevated serum ALT; or
   (b) Liver biopsy

**Authority required**

Treatment, as sole PBS-subsidised therapy, in a patient with chronic hepatitis B with cirrhosis who is nucleoside analogue naive and who has detectable HBV DNA.

Persons with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy.

### telbivudine 600 mg tablet, 28

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**TENOFOVIR**

**Authority required**

HIV infection

Treatment Phase: Initial

**Clinical criteria:**

Patient must be antiretroviral treatment naive, **AND**

The treatment must be in combination with other antiretroviral agents.

**Authority required**

HIV infection

Treatment Phase: Continuing

**Clinical criteria:**

Patient must have previously received PBS-subsidised therapy for HIV infection, **AND**

The treatment must be in combination with other antiretroviral agents.

**Authority required**

Chronic hepatitis B

**Clinical criteria:**

Patient must not have cirrhosis, **AND**

Patient must be nucleoside analogue 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.

**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.

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.

**Authority required**

Chronic hepatitis B

**Clinical criteria:**

Patient must not have cirrhosis, **AND**

Patient must have failed antiviral therapy, **AND**

Patient must have repeatedly elevated serum ALT levels while on concurrent antiviral therapy of greater than or equal to 6 months duration, in conjunction with documented chronic hepatitis B infection; **OR**

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 antiviral therapy, except in patients with evidence of poor compliance.

**Authority required**

Chronic hepatitis B

**Clinical criteria:**

Patient must have cirrhosis, **AND**

Patient must have failed antiviral therapy, **AND**

Patient must have detectable HBV DNA.
Persons with Child’s class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy.

**Note**
Patients may receive treatment in combination with lamivudine but not with other PBS-subsidised antihepadnaviral therapy.

---

**tenofovir disoproxil fumarate 300 mg tablet, 30**

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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.

---

**zidovudine 100 mg capsule, 100**

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**zidovudine 250 mg capsule, 40**

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<td>*1279.54</td>
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**zidovudine 50 mg/5 mL oral liquid, 200 mL**

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**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.

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**efavirenz 200 mg tablet, 90**

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**efavirenz 30 mg/mL oral liquid, 180 mL**

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**efavirenz 600 mg tablet, 30**

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<td>5</td>
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<td>*571.64</td>
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</tbody>
</table>

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**ETRAVIREN**

*Authority required*
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.

eetravirine 200 mg tablet, 60

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**NEVIRAPINE**

- **Authority required**
- **HIV infection**
- **Treatment Phase: Initial**
- **Clinical criteria:**
  - Patient must have been stabilised on nevirapine immediate release, **AND**
  - The treatment must be in combination with other antiretroviral agents.

- **Authority required**
- **HIV infection**
- **Treatment Phase: Continuing**
- **Clinical criteria:**
  - Patient must have previously received PBS-subsidised therapy for HIV infection, **AND**
  - The treatment must be in combination with other antiretroviral agents.

nevirapine 400 mg tablet: modified release, 30 tablets

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**NEVIRAPINE**

- **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.

nevirapine 10 mg/mL oral liquid, 240 mL

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nevirapine 200 mg tablet, 60

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**RILPIVIRINE**

- **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.
ABACAVIR + LAMIVUDINE

**Authority required**
HIV infection

**Clinical criteria:**
Patient must be antiretroviral treatment naive, AND
The treatment must be in combination with other antiretroviral agents.

**Population criteria:**
Patient must be aged 12 years or older, AND
Patient must weigh 40 kg or more.

**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.

**Population criteria:**
Patient must be aged 12 years or older, AND
Patient must weigh 40 kg or more.

**abacavir 600 mg + lamivudine 300 mg tablet, 30**

<table>
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ABACAVIR + LAMIVUDINE + ZIDOVUDINE

**Authority required**
HIV infection

**Clinical criteria:**
Patient must be antiretroviral treatment naive.

**Population criteria:**
Patient must be aged 12 years or older, AND
Patient must weigh 40 kg or more.

**Authority required**
HIV infection

**Clinical criteria:**
Patient must have previously received PBS-subsidised therapy for HIV infection.

**Population criteria:**
Patient must be aged 12 years or older, AND
Patient must weigh 40 kg or more.

**abacavir 300 mg + lamivudine 150 mg + zidovudine 300 mg tablet, 60**

<table>
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DOLUTEGRAVIR + ABACAVIR + LAMIVUDINE

**Authority required**
HIV infection

**Clinical criteria:**
Patient must be antiretroviral treatment naive.

**Population criteria:**
Patient must be aged 12 years or older, AND
Patient must weigh 40 kg or more.

**Authority required**
HIV infection

**Clinical criteria:**
Patient must have previously received PBS-subsidised therapy for HIV infection.
Population criteria:
Patient must be aged 12 years or older, and
Patient must weigh 40 kg or more.

**dolutegravir 50 mg + abacavir 600 mg + lamivudine 300 mg tablet, 30**

<table>
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**EMTRICITABINE + RILPIVIRINE + TENOFOVIR**

**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.

**emtricitabine 200 mg + rilpivirine 25 mg + tenofovir disoproxil fumarate 300 mg tablet, 30**

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</table>

**LAMIVUDINE + ZIDOVUDINE**

**Authority required**
HIV infection
Treatment Phase: Initial

**Clinical criteria:**
Patient must be antiretroviral treatment naive, and
The treatment must be in combination with other antiretroviral agents.

**Authority required**
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.

**lamivudine 150 mg + zidovudine 300 mg tablet, 60**

<table>
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**LOPINAVIR + RITONAVIR**

**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.

**lopinavir 100 mg + ritonavir 25 mg tablet, 60**

<table>
<thead>
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**lopinavir 200 mg + ritonavir 50 mg tablet, 120**

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lopinavir 400 mg/5 mL + ritonavir 100 mg/5 mL oral liquid, 60 mL

6341R

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- **TENOFOVIR + EMTRICITABINE**
  - **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.

- **TENOFOVIR disoproxil fumarate 300 mg + emtricitabine 200 mg tablet, 30**

6468K

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- **TENOFOVIR + EMTRICITABINE + EFAVIRENZ**
  - **Authority required**
  - HIV infection
  - **Clinical criteria:**
    - Patient must be antiretroviral treatment naive.
  - **Authority required**
  - HIV infection
  - **Clinical criteria:**
    - Patient must have previously received PBS-subsidised therapy for HIV infection.

- **TENOFOVIR disoproxil fumarate 300 mg + emtricitabine 200 mg + efavirenz 600 mg tablet, 30**

9650X

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- **TENOFOVIR + EMTRICITABINE + ELVITEGRAVIR + COBICISTAT**
  - **Authority required**
  - HIV infection
  - **Clinical criteria:**
    - Patient must be antiretroviral treatment naive.
  - **Authority required**
  - HIV infection
  - **Clinical criteria:**
    - Patient must have previously received PBS-subsidised therapy for HIV infection.

- **TENOFOVIR disoproxil fumarate 300 mg + emtricitabine 200 mg + elvitegravir 150 mg + cobicistat 150 mg tablet, 30**

10085T

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- **Other antivirals**

- **DOLUTEGRAVIR**
  - **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.
ANTIINFECTIVES FOR SYSTEMIC USE

Clinical criteria:
Patient must have previously received PBS-subsidised therapy for HIV infection, AND
The treatment must be in combination with other antiretroviral agents.

dolutegravir 50 mg tablet, 30

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- **ENFUVIRTIDE**
  **Authority required**
  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.

enfuvirtide 90 mg injection [60 x 90 mg vials] (&) inert substance diluent [60 x 1.1 mL vials], 1 pack

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- **MARAVIROC**
  **Authority required**
  Treatment, in addition to optimised background therapy in combination with other antiretroviral agents, of an antiretroviral experienced patient infected with only CCR5-tropic HIV-1, who, after each of at least three different antiretroviral regimens that have included one drug from at least 3 different antiretroviral classes, has experienced virological failure or clinical failure or genotypic resistance. A tropism assay to determine CCR5 only strain status is required prior to initiation. Individuals with CXCR4 tropism demonstrated at any time point are not eligible.
  Virological failure is defined as a viral load greater than 400 copies per mL on two consecutive occasions, while clinical failure is linked to emerging signs and symptoms of progressing HIV infection or treatment-limiting toxicity.

maraviroc 150 mg tablet, 60

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maraviroc 300 mg tablet, 60

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- **RALTEGRAVIR**
  **Authority required**
  HIV infection
  Treatment Phase: Initial
  **Clinical criteria:**
  Patient must be antiretroviral treatment naive, AND
  The treatment must be in combination with other antiretroviral agents.

  **Authority required**
  HIV infection
  Treatment Phase: Continuing
  **Clinical criteria:**
  Patient must have previously received PBS-subsidised therapy for HIV infection, AND
  The treatment must be in combination with other antiretroviral agents.

raltegravir 400 mg tablet, 60

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- **RALTEGRAVIR**
  **Authority required**
  HIV infection
  Treatment Phase: Initial
  **Clinical criteria:**
  The treatment must be in combination with other antiretroviral agents, AND
  Patient must be antiretroviral experienced with at least 6 months therapy with 2 alternate classes of anti-retroviral therapy, AND
  Patient must have a CD4 count of less than 500 per cubic millimetre; OR
  Patient must have symptomatic HIV disease.
  **Population criteria:**
Patient must be aged 2 years or older.

**Authority required**

HIV infection

**Clinical criteria:**
The treatment must be in combination with other antiretroviral agents, AND
Patient must have previously received PBS-subsidised therapy for HIV infection.

**Population criteria:**
Patient must be aged 2 years or older.

**raltegravir 100 mg tablet:** chewable, 60

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**raltegravir 25 mg tablet:** chewable, 60

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**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
Special Pricing Arrangements apply.

azacitidine 100 mg injection, 1 x 100 mg vial

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### AZACITIDINE

**Authority required**

Continuing 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% blasts and multi-lineage dysplasia, according to World Health Organisation (WHO) Classification; who has previously been issued with an authority prescription for azacitidine and does not have progressive disease.

Authority applications for continuing treatment may be made by telephone on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Up to six cycles will be authorised

**Note**

Any queries concerning the arrangements to prescribe azacitidine may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.
Written applications for authority to prescribe azacitidine should be forwarded to:
Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001
Special Pricing Arrangements apply.

### 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

doxorubicin hydrochloride-pegylated liposomal 20 mg/10 mL injection, 1 x 10 mL vial

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### IMMUNOSTIMULANTS

#### 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 3 separate cycles, and, either having experienced a life-threatening infectious episode requiring hospitalisation and treatment with intravenous antibiotics, or having recurrent clinically significant infections (a minimum of 3 in the previous 12 months))

**Authority required**
A patient with inoperable Stage III, IVA or IVB squamous cell carcinoma of the oral cavity, larynx, oropharynx or hypopharynx receiving neoadjuvant treatment with docetaxel in combination with cisplatin and fluorouracil who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned

**Authority required**
Mobilisation of peripheral blood progenitor cells, in a normal volunteer, for use in allogeneic transplantation

**Authority required**
A patient receiving marrow-ablative chemotherapy and subsequent bone marrow transplantation

**Authority required**
A patient with a non-myeloid malignancy receiving marrow-ablative chemotherapy and subsequent autologous peripheral blood progenitor cell transplantation

**Authority required**
A patient with breast cancer receiving standard dose adjuvant chemotherapy who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned

**Authority required**
A patient receiving chemotherapy for B-cell chronic lymphocytic leukaemia with fludarabine and cyclophosphamide who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned

**Authority required**
A patient receiving first-line chemotherapy for Hodgkin disease who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned

**Authority required**
A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in acute lymphoblastic leukaemia

**Authority required**
A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in breast cancer (adjuvant chemotherapy with docetaxel in combination with an anthracycline and cyclophosphamide)

**Authority required**
A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in germ cell tumours

**Authority required**
A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in infants and children with CNS tumours

**Authority required**
A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in neuroblastoma
ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

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)

filgrastim 120 microgram/0.2 mL injection, 10 x 0.2 mL syringes

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filgrastim 300 microgram/0.5 mL injection, 10 x 0.5 mL syringes

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filgrastim 300 microgram/0.5 mL injection, 10 x 0.5 mL syringes

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filgrastim 300 microgram/0.5 mL injection, 10 x 0.5 mL syringes

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filgrastim 300 microgram/0.5 mL injection, 5 x 0.5 mL syringes

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filgrastim 300 microgram/mL injection, 10 x 1 mL vials

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filgrastim 480 microgram/0.5 mL injection, 10 x 0.5 mL syringes

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filgrastim 480 microgram/0.5 mL injection, 10 x 0.5 mL syringes

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filgrastim 480 microgram/0.5 mL injection, 5 x 0.5 mL syringes

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filgrastim 480 microgram/0.8 mL injection, 10 x 0.8 mL syringes

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filgrastim 480 microgram/1.6 mL injection, 10 x 1.6 mL vials

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LENOGRASITIM

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

LENOGRASTIM Powder for injection 13,400,000 i.u. (105 micrograms) vial, 10

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LENOGRASTIM Powder for injection 33,600,000 i.u. (263 micrograms) vial, 10

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**PEGFILGRASTIM**

**Authority required**

For use in a patient undergoing induction and consolidation therapy for acute myeloid leukaemia

**Authority required**

A patient with breast cancer receiving standard dose adjuvant chemotherapy who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned

**Authority required**

A patient receiving chemotherapy for B-cell chronic lymphocytic leukaemia with fludarabine and cyclophosphamide who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned

**Authority required**

A patient receiving first-line chemotherapy for Hodgkin disease who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned

**Authority required**
A patient receiving chemotherapy for myeloma who has had a prior episode of febrile neutropenia, and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned

**Authority required**

A patient with inoperable Stage III, IVa or IVb squamous cell carcinoma of the oral cavity, larynx, oropharynx or hypopharynx receiving neoadjuvant treatment with docetaxel in combination with cisplatin and fluorouracil who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned

**Authority required**

A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in acute lymphoblastic leukaemia

**Authority required**

A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in breast cancer (adjunctive chemotherapy with docetaxel in combination with an anthracycline and cyclophosphamide)

**Authority required**

A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in germ cell tumours

**Authority required**

A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in infants and children with CNS tumours

**Authority required**

A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in neuroblastoma

**Authority required**

A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in non-Hodgkin lymphoma (aggressive grades; or low grade receiving an anthracycline-containing regimen)

**Authority required**

A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in relapsed Hodgkin disease

**Authority required**

A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in sarcoma

**Authority required**

A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in Hodgkin disease (first-line chemotherapy with escalated BEACOPP)

**Interferons**

### INTERFERON ALFA-2A

**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.

**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

**interferon alfa-2a 3 million international units/0.5 mL injection, 1 x 0.5 mL syringe**

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interferon alfa-2a 4.5 million international units/0.5 mL injection, 1 x 0.5 mL syringe
6211X

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interferon alfa-2a 6 million international units/0.5 mL injection, 1 x 0.5 mL syringe
6212Y

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interferon alfa-2a 9 million international units/0.5 mL injection, 1 x 0.5 mL syringe
6213B

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**INTERFERON ALFA-2B**

### 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.

### Authority required
Adjunctive therapy of malignant melanoma following surgery in patients with nodal involvement in the chronic phase

### 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

interferon alfa-2b 10 million international units/mL injection, 5 x 1 mL vials
6246R

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interferon alfa-2b 18 million international units/1.2 mL injection, 1 x 1.2 mL cartridge
6253D

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interferon alfa-2b 18 million international units/3 mL injection, 1 x 3 mL vial
6218G

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interferon alfa-2b 25 million international units/2.5 mL injection, 1 x 2.5 mL vial
6219H

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interferon alfa-2b 30 million international units/1.2 mL injection, 1 x 1.2 mL cartridge
6254E

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interferon alfa-2b 60 million international units/1.2 mL injection, 1 x 1.2 mL cartridge
6255F

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**INTERFERON GAMMA-1B**

### Authority required
Treatment of chronic granulomatous disease in patients with frequent and severe infections despite adequate prophylaxis with antimicrobial agents

interferon gamma-1b 2 million international units (100 microgram/0.5 mL) injection, 6 x 0.5 mL vials
6148N

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<td>*2768.56</td>
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PEGINTERFERON ALFA-2A

**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.

**Authority required**
Treatment, as sole PBS-subsidised therapy, in a patient with chronic hepatitis B without cirrhosis who satisfies all of the following criteria:
1. Elevated HBV DNA levels - greater than 20,000 IU/mL (100,000 copies/mL) if HBeAg positive, or greater than 2,000 IU/mL (10,000 copies/mL) if HBeAg negative - in conjunction with documented chronic hepatitis B infection;
2. Evidence of chronic liver injury as determined by:
   a. Confirmed elevated serum ALT; or
   b. Liver biopsy;
3. Has received no prior peginterferon alfa therapy for the treatment of hepatitis B

**Authority required**
Treatment, as sole PBS-subsidised therapy, in a patient with chronic hepatitis B with cirrhosis who has detectable HBV DNA. Persons with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy.

Treatment is limited to 1 course of treatment for a duration of up to 48 weeks

**Note**
Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:
(a) a nurse educator/counsellor for patients; and
(b) 24 hour access by patients to medical advice; and
(c) an established liver clinic; and
(d) facilities for safe liver biopsy.

| Peginterferon alfa-2a 135 microgram/0.5 mL injection, 4 x 0.5 mL syringes |
|-----------------------------|----------------|----------------|----------------|----------------|
| Max Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
| 6439X | 2 | 5 | .. | *2378.56 | Pegasys [RO] |

| Peginterferon alfa-2a 180 microgram/0.5 mL injection, 4 x 0.5 mL syringes |
|-----------------------------|----------------|----------------|----------------|----------------|
| Max Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
| 6449K | 2 | 5 | .. | *2747.22 | Pegasys [RO] |

**PEGINTERFERON ALFA-2A (&) RIBAVIRIN**

**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.

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.

**Authority required**
Chronic genotype 1 hepatitis C infection

**Clinical criteria:**
Patient must have compensated liver disease, AND
Patient must have failed prior treatment with interferon based therapies (non-pegylated or pegylated), AND
Patient must have received no more than one prior treatment with interferon alfa or peginterferon alfa for hepatitis C if using peginterferon and ribavirin without an NS3 protease inhibitor, or, in triple combination therapy with boceprevir; OR
Patient must have received prior treatment with interferon alfa or peginterferon alfa for hepatitis C if using peginterferon and ribavirin in triple combination therapy with telaprevir; OR
Patient must have received prior treatment with interferon alfa or peginterferon alfa for hepatitis C if using peginterferon and ribavirin in triple combination therapy with simeprevir, AND
The treatment must be limited to a maximum duration of 24 weeks in patients using peginterferon and ribavirin in triple combination therapy with telaprevir who were prior treatment 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 24 weeks in patients using peginterferon and ribavirin in triple combination therapy with simeprevir who were prior treatment relapers and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at week 4; OR

The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin without an NS3 protease inhibitor; OR

The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin in triple combination therapy with boceprevir who: (i) were prior treatment null responders; or (ii) were prior treatment partial responders or relapers and in whom plasma HCV RNA is detectable by an HCV RNA qualitative assay at week 8, and undetectable by an HCV RNA qualitative assay at week 12; or (iii) have hepatic cirrhosis; OR

The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin in triple combination therapy with telaprevir who: (i) were prior treatment partial or null responders; or (ii) were prior treatment relapers and for whom the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is detectable but less than or equal to 1000 IU/mL; or (iii) have hepatic cirrhosis; OR

The treatment must cease in patients using peginterferon and ribavirin without an NS3 protease inhibitor if HCV RNA is detectable by an HCV RNA qualitative assay at week 12, AND

The treatment must cease in patients using peginterferon and ribavirin in combination with boceprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12, AND

The treatment must cease in patients using peginterferon and ribavirin in combination with boceprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24, AND

The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is greater than or equal to 25 IU/mL, AND

The treatment must cease in patients using peginterferon and ribavirin in combination with simeprevir if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is detectable by an HCV RNA qualitative assay at week 12, AND

The treatment must cease in patients using peginterferon and ribavirin in combination with simeprevir if 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 HCV RNA is detectable but less than or equal to 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 simeprevir if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is detectable by an HCV RNA qualitative assay at week 24, AND

The treatment must cease in patients using peginterferon and ribavirin in combination with simeprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 4, AND

The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable but less than 25 IU/mL, AND

The treatment must cease in patients using peginterferon and ribavirin in combination with simeprevir if HCV RNA is detectable but less than or equal to 1000 IU/mL; or (iii) have hepatic cirrhosis; OR

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.

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 in triple combination therapy with telaprevir and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at week 4; OR
The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin without an NS3 protease inhibitor; OR
The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin in triple combination therapy with boceprevir and in whom plasma HCV RNA is detectable by an HCV RNA qualitative assay at week 8, and undetectable by an HCV RNA qualitative assay at week 24; or (ii) using peginterferon and ribavirin in triple combination therapy with boceprevir who have hepatic cirrhosis; OR
The treatment must be limited to a maximum duration of 48 weeks in patients: (i) using peginterferon and ribavirin in triple combination therapy with telaprevir and for whom the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is detectable but less than or equal to 1000 IU/mL; or (ii) using peginterferon and ribavirin in triple combination therapy with telaprevir who have hepatic cirrhosis; OR
The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin in triple combination therapy with simeprevir and for whom the results of an HCV RNA qualitative assay at week 4 show that the plasma HCV RNA is detectable but less than 25 IU/mL, AND
The treatment must cease in patients using peginterferon and ribavirin without an NS3 protease inhibitor unless the results of an HCV RNA quantitative assay at week 12 (performed at the same laboratory using the same test) show that plasma HCV RNA has become undetectable or the viral load has decreased by at least a 2 log drop, AND
The treatment must cease in patients using peginterferon and ribavirin in combination with boceprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24, AND
The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is greater than 1000 IU/mL, AND
The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24, AND
The treatment must cease in patients using peginterferon and ribavirin in combination with simeprevir if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is greater than or equal to 25 IU/mL, AND
The treatment must cease in patients using peginterferon and ribavirin in combination with simeprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12, AND
The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24, AND
The treatment must cease in patients using peginterferon and ribavirin in combination with simeprevir if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is greater than 25 IU/mL, AND
The treatment must cease in patients using peginterferon and ribavirin in combination with simeprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12, AND
The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if 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 telaprevir who have hepatic cirrhosis; OR
The treatment must be limited to a maximum duration of 48 weeks in 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 in 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 without hepatic cirrhosis or bridging fibrosis, AND

**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.

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

**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.

**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.

### PEGINTERFERON ALFA-2B (&) RIBAVIRIN

**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.

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.

**Authority required**
Chronic genotype 1 hepatitis C infection

**Clinical criteria:**
Patient must have compensated liver disease, **AND**
Patient must have failed prior treatment with interferon based therapies (non-pegylated or pegylated), **AND**
Patient must have received no more than one prior treatment with interferon alfa or peginterferon alfa for hepatitis C if using peginterferon and ribavirin without an NS3 protease inhibitor, or, in triple combination therapy with boceprevir; **OR**
Patient must have received prior treatment with interferon alfa or peginterferon alfa for hepatitis C if using peginterferon and ribavirin in triple combination therapy with telaprevir; **OR**
Patient must have received prior treatment with interferon alfa or peginterferon alfa for hepatitis C if using peginterferon and ribavirin in triple combination therapy with simeprevir, **AND**

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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 quantitative assay at weeks 4 and 12; OR
The treatment must be limited to a maximum duration of 36 weeks in patients using peginterferon and ribavirin in triple combination therapy with boceprevir who were prior treatment partial responders or relapers and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at weeks 8 and 12; OR
The treatment must be limited to a maximum duration of 24 weeks in patients using peginterferon and ribavirin in triple combination therapy with simeprevir who were prior treatment partial responders or relapers and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at week 4; OR
The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin without an NS3 protease inhibitor; OR
The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin in triple combination therapy with boceprevir who: (i) were prior treatment null responders; or (ii) were prior treatment partial responders or relapers and in whom plasma HCV RNA is detectable by an HCV RNA qualitative assay at week 4, and undetectable by an HCV RNA qualitative assay at week 8; and (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 25 IU/mL; and (iii) have hepatic cirrhosis; OR
The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin without an NS3 protease inhibitor if HCV RNA is detectable by an HCV RNA qualitative assay at week 4 show that the plasma HCV RNA is detectable but less than 25 IU/mL, AND
The treatment must cease in patients using peginterferon and ribavirin without an NS3 protease inhibitor 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 quantitative 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 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 HCV RNA is detectable by an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is greater than 25 IU/mL, AND
The treatment must cease in patients using peginterferon and ribavirin in combination with simeprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 4, AND
The treatment must cease in patients using peginterferon and ribavirin in combination with simeprevir if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is detectable by an HCV RNA qualitative assay at week 12, AND
The treatment must cease in patients using peginterferon and ribavirin in combination with simeprevir if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is greater than or equal to 25 IU/mL, AND
The treatment must cease in patients using peginterferon and ribavirin in combination with simeprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12, AND
The treatment must cease in patients using peginterferon and ribavirin in combination with simeprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24.

Population criteria:
Patient must be aged 18 years or older, AND
Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

Treatment criteria:
Must be treated in an accredited treatment centre.
Evidence of chronic genotype 1 hepatitis C infection (repeatedly anti-HCV positive and HCV RNA positive) must be documented in the patient’s medical records.

Authority required
Chronic genotype 1 hepatitis C infection Clinical criteria:
Patient must have compensated liver disease, AND
Patient must not have received prior interferon alfa or peginterferon alfa treatment for hepatitis C, AND
The treatment must be limited to a maximum duration of 24 weeks in patients using peginterferon and ribavirin in triple combination therapy with telaprevir and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at weeks 4 and 12; OR
The treatment must be limited to a maximum duration of 28 weeks in patients using peginterferon and ribavirin in triple combination therapy with boceprevir and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at weeks 8 and 24; OR
The treatment must be limited to a maximum duration of 24 weeks in patients using peginterferon and ribavirin in triple combination therapy with simeprevir and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at week 4; OR
The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin without an NS3 protease inhibitor; OR
The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin in triple combination therapy with boceprevir and in whom plasma HCV RNA is detectable by an HCV RNA qualitative assay at week 8, and undetectable by an HCV RNA qualitative assay at week 24; or (ii) using peginterferon and ribavirin in triple combination therapy with boceprevir who have hepatic cirrhosis; OR
The treatment must be limited to a maximum duration of 48 weeks in patients: (i) using peginterferon and ribavirin in triple combination therapy with telaprevir and for whom the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is detectable but less than or equal to 1000 IU/mL; or (ii) using peginterferon and ribavirin in triple combination therapy with telaprevir who have hepatic cirrhosis; OR
The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin in triple combination therapy with simeprevir and for whom the results of an HCV RNA qualitative assay at week 4 show that the plasma HCV RNA is detectable but less than 25 IU/mL. AND
The treatment must cease in patients using peginterferon and ribavirin without an NS3 protease inhibitor unless the results of an HCV RNA quantitative assay at week 12 (performed at the same laboratory using the same test) show that plasma HCV RNA has become undetectable or the viral load has decreased by at least a 2 log drop, AND
The treatment must cease in patients using peginterferon and ribavirin in combination with boceprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24, AND
The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is greater than 1000 IU/mL, AND
The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12, AND
The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24.

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.

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

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.

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 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 |
|---|---|---|---|---|
| Max Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
| 6407F | 2 | 5 | *3538.34 | Pegatron [MK] |

| 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 |
|---|---|---|---|---|
| Max Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
| 6409H | 2 | 5 | *4126.28 | Pegatron [MK] |

| 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 |
|---|---|---|---|---|
| Max Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
| 6410J | 2 | 5 | *4126.28 | Pegatron [MK] |

| 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 |
|---|---|---|---|---|
| Max Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
| 9634C | 2 | 5 | *4411.24 | Pegatron [MK] |

| 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 |
|---|---|---|---|---|
| Max Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer |
| 6402Y | 2 | 5 | *2754.42 | Pegatron [MK] |

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**PEGINTERFERON ALFA-2B (&) RIBAVIRIN**

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.

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.

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
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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.

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 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.
For patients who are viral negative at week 12, an HCV RNA qualitative assay at week 24 is unnecessary.

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 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.

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 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
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 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 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 quantitative 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.

**Authority required**

Chronic genotype 1 hepatitis C infection

**Clinical criteria:**

Patient must have compensated liver disease, **AND**

Patient must have failed prior treatment with interferon based therapies (non-pegylated or pegylated), **AND**

Patient must have received no more than one prior treatment with interferon alfa or peginterferon alfa for hepatitis C if using peginterferon and ribavirin without an NS3 protease inhibitor, or, in triple combination therapy with boceprevir; **OR**

Patient must have received prior treatment with interferon alfa or peginterferon alfa for hepatitis C if using peginterferon and ribavirin in triple combination therapy with telaprevir; **OR**

Patient must have received prior treatment with interferon alfa or peginterferon alfa for hepatitis C if using peginterferon and ribavirin in triple combination therapy with simeprevir, **AND**

The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin without an NS3 protease inhibitor; **OR**

The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin in triple combination therapy with boceprevir who: (i) were prior treatment null responders; or (ii) were prior treatment partial responders or relapsers and in whom plasma HCV RNA is detectable by an HCV RNA qualitative assay at week 12; **OR**

The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin in triple combination therapy with simeprevir who: (i) were prior treatment partial responders or relapsers and in whom plasma HCV RNA is undetectable by an HCV RNA quantitative 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 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 week 4; **OR**

The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin without an NS3 protease inhibitor 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 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 HCV RNA is detectable by an HCV RNA qualitative assay at week 12. **AND**

The treatment must cease in patients using peginterferon and ribavirin in combination with simeprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12. **AND**

The treatment must cease in patients using peginterferon and ribavirin in combination with simeprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24.

**Population criteria:**

Patient must be aged 18 years or older, **AND**

Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

**Treatment criteria:**
Must be treated in an accredited treatment centre.
Evidence of chronic genotype 1 hepatitis C infection (repeatedly anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.

**Authority required**
Chronic genotype 1 hepatitis C infection

**Clinical criteria:**
Patient must have compensated liver disease, **AND** Patient must not have received prior interferon alfa or peginterferon alfa treatment for hepatitis C, **AND** The treatment must be limited to a maximum duration of 24 weeks in patients using peginterferon and ribavirin in triple combination therapy with telaprevir and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at weeks 4 and 12; **OR** The treatment must be limited to a maximum duration of 28 weeks in patients using peginterferon and ribavirin in triple combination therapy with boceprevir and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at weeks 8 and 24; **OR** The treatment must be limited to a maximum duration of 24 weeks in patients using peginterferon and ribavirin in triple combination therapy with boceprevir and in whom plasma HCV RNA is undetectable by an HCV RNA quantitative assay at week 4; **OR** The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin without an NS3 protease inhibitor; **OR**

The treatment must be limited to a maximum duration of 48 weeks in patients: (i) using peginterferon and ribavirin in triple combination therapy with boceprevir and in whom plasma HCV RNA is detectable by an HCV RNA qualitative assay at week 8, and undetectable by an HCV RNA qualitative assay at week 24; or (ii) using peginterferon and ribavirin in triple combination therapy with boceprevir who have hepatic cirrhosis; **OR**

The treatment must be limited to a maximum duration of 48 weeks in patients: (i) using peginterferon and ribavirin in triple combination therapy with telaprevir and for whom the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is detectable but less than or equal to 1000 IU/mL; or (ii) using peginterferon and ribavirin in triple combination therapy with telaprevir who have hepatic cirrhosis; **OR**

The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin in triple combination therapy with simeprevir and for whom the results of an HCV RNA quantitative assay at week 4 show that the 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 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, **AND**

The treatment must cease in patients using peginterferon and ribavirin in combination with simeprevir if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is greater than or equal to 25 IU/mL. **AND**

The treatment must cease in patients using peginterferon and ribavirin in combination with simeprevir if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is detectable by an HCV RNA qualitative assay at week 12, **AND**

The treatment must cease in patients using peginterferon and ribavirin in combination with simeprevir if the plasma HCV RNA is undetectable by an HCV RNA quantitative assay at week 8, and undetectable by an HCV RNA qualitative assay at week 24; OR

The treatment must cease in patients using peginterferon and ribavirin in combination with boceprevir and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at week 8 and 24; OR

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 (repeatedly 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 quantitative assay at week 24 is unnecessary.

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

**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.

**Note**
Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:
(a) a nurse educator/counsellor for patients; and
(b) 24-hour access by patients to medical advice; and
(c) an established liver clinic.

**Other immunostimulants**
\section*{PLERIXAFOR}

\textbf{Authority required}
Mobilisation of haematopoietic stem cells

\textbf{Clinical criteria:}
The treatment must be in combination with granulocyte-colony stimulating factor (G-CSF), \textbf{AND}
Patient must have lymphoma; OR
Patient must have multiple myeloma, \textbf{AND}
Patient must require autologous stem cell transplantation, \textbf{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.

\textbf{Evidence that the patient meets the PBS restriction criteria must be recorded in the patient's medical records.}

\textbf{Note}
Applications for increased maximum quantities will only be authorised for patients with body weight greater than 100 kg.

\begin{verbatim}
plerixafor 24 mg/1.2 mL injection: subcutaneous infusion, 1 x 1.2 mL vial
10084R
Max Qty Packs No.of Rpts Premium $ DPMQ $ Brand Name and Manufacturer
1 1 .. 7037.76 Mozobil [GZ]
\end{verbatim}

\section*{IMMUNOSUPPRESSANTS}

\textbf{Selective immunosuppressants}

\section*{ABATACEPT}

\textbf{Authority required}
Severe active rheumatoid arthritis

\textbf{Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months)}

\textbf{Clinical criteria:}
Patient must have severe active rheumatoid arthritis, \textbf{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, \textbf{AND}
Patient must not have failed previous PBS-subsidised treatment with this drug for this condition, and have not already failed, or ceased to respond to, PBS-subsidised bDMARD treatment for this condition 5 times, \textbf{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 on of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR
Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR
Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above, must include at least 3 months continuous treatment with each of at least 2 DMARDs, with one or more of the following DMARDs being used in place of the DMARDs which are contraindicated or not tolerated: (i) azathioprine at a dose of at least 1 mg/kg per day; and/or (ii) cyclosporin at a dose of at least 2 mg/kg/day; and/or (iii) sodium aurothiomalate at a dose of 50 mg weekly. \textbf{AND}
Patient must not receive more than 16 weeks of treatment under this restriction, \textbf{AND}
The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

\textbf{Population criteria:}
Patient must be aged 18 years or older.

\textbf{Treatment criteria:}
Must be treated by a rheumatologist; OR
Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab or tocilizumab.

If methotrexate is contraindicated according to the TGA-approved Product Information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.
The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or tolerances. The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance and dose for each DMARD must be provided in the authority application.

The authority application must be made in writing and must include:

1. A completed authority prescription form; and
2. A completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form; and
3. A signed patient acknowledgement.

At the time of authority application, medical practitioners should request the appropriate number of vials to provide sufficient drug, based on the weight of the patient, for a single infusion. Up to a maximum of 4 repeats will be authorised.

Assessment of a patient's response to an initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted no later than 1 month from the date of completion of this initial course of treatment.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

Applications for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

- An elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either
  - a total active joint count of at least 20 active (swollen and tender) joints; or
  - (a) at least 4 active joints from the following list of major joints:
    (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
    (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).
  - The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Where the baseline joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP is provided with the initial application, the same marker will be used to determine response.

**Note**

The Department of Human Services website (www.humanservices.gov.au) has details of the toxicities, including severity, which will be accepted for the following purposes:

- (a) exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose;
- (b) substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial;
- (c) exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy.

**Special Pricing Arrangements apply.**

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or re-commencement of treatment after break of less than 24 months).

**Clinical criteria:**

Patient must have a documented history of severe active rheumatoid arthritis, AND

Patient must have received prior PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition and are eligible to receive further bDMARD therapy, AND

Patient must not receive more than 16 weeks of treatment under this restriction, AND

The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

**Population criteria:**

Patient must be aged 18 years or older.
Treatment criteria:
Must be treated by a rheumatologist; OR
Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.
For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab or tocilizumab.
The authority application must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.
At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug, based on the weight of the patient, for a single infusion. Up to a maximum of 4 repeats will be authorised.
Applications for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient’s most recent course of PBS-subsidised treatment, within the timeframes specified below.
Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.
Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.
Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.
If a patient fails to demonstrate a response to a treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.
A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD.
An adequate response to treatment is defined as:
- an ESR no greater than 20 mm per hour or a CRP level no greater than 15 mg per L.
- an active joint count of fewer than 10 active (swollen and tender) joints; or
- a PGA no greater than 3/10.
- 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
TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying anti-rheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab) and the T-cell co-stimulation modulator (abatacept).
Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.
In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.
A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:
- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.
For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.
A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has 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 has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 2); or
- (iii) a patient has received prior PBS-subsidised therapy with a bDMARD while they continue to show a response to therapy;
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab and tocilizumab, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:

Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient’s weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:

A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept patients:

Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

the Department of Human Services will determine whether a response to treatment has been demonstrated based on the...
baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements. To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-comminating patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Authority required
Severe active rheumatoid arthritis
Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months) or Initial 2 (change or recommencement of treatment after break of less than 24 months) – balance of supply.

Clinical criteria:
Patient must have received insufficient therapy with this drug under the Initial 1 (new patient or patient recommencing treatment after break of more than 24 months) restriction to complete 16 weeks treatment; OR
Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement of treatment after break of less than 24 months) restriction to complete 16 weeks treatment, AND
The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Treatment criteria:
Must be treated by a rheumatologist; OR
Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Note
Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Authority required
Severe active rheumatoid arthritis
Treatment Phase: Continuing treatment.

Clinical criteria:
Patient must have a documented history of severe active rheumatoid arthritis, AND
Patient must have demonstrated an adequate response to treatment with this drug, AND
Patient must have received this drug as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment, AND
Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction, AND
The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

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

Treatment criteria:
Must be treated by a rheumatologist; OR
Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab or tocilizumab.

An adequate response to treatment is defined as:
an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;
AND either of the following:
(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:
(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).
Where the baseline active joint count is based on total active joints (i.e., more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) a completed Authority prescription form; and
(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners should request the appropriate number of vials to provide sufficient drug, based on the weight of the patient, for a single infusion. Up to a maximum of 5 repeats will be authorised.

All applications for continuing treatment with this drug must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826

HOBART TAS 7001

TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab) and the T-cell co-stimulation modulator (abatacept).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:

- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with a PBS-subsidised bDMARD was stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab and tocilizumab, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a
minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks. Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:

- Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:

- A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

- Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug 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.

(2) Swapping therapy.

- Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

- Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

- A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept patients:

- Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

- In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

- To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

- PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

- To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

- The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD.

- However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.

- To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.
Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

**Authority required**
Severe active rheumatoid arthritis
Treatment Phase: Continuing Treatment – balance of supply.

**Clinical criteria:**
Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, AND
The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Treatment criteria:**
Must be treated by a rheumatologist; OR
Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Note**
Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

### abatacept 250 mg injection, 1 x 250 mg vial

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### ALEMTUZUMAB

**Authority required**
Multiple sclerosis
Treatment Phase: Continuing

**Clinical criteria:**
Patient must have previously been issued with an authority prescription for this drug, AND
Patient must not show continuing progression of disability while on treatment with this drug, AND
Patient must not receive more than one PBS-subsidised treatment per year, AND
The treatment must be as monotherapy, AND
Patient must have demonstrated compliance with, and an ability to tolerate this therapy.

**Treatment criteria:**
Must be treated by a neurologist.

**Note**
Neurologists prescribing PBS-subsidised alemtuzumab must be registered with the Lemtrada monitoring program.
Special Pricing Arrangements apply.
No increase in the maximum quantity or number of units may be authorised.
No increase in the maximum number of repeats may be authorised.

### alemtuzumab 12 mg/1.2 mL injection, 1 x 1.2 mL vial

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Patient must be ambulatory (without assistance or support).

**Treatment criteria:**
Must be treated by a neurologist.
Where applicable, the date of the magnetic resonance imaging scan must be provided with the authority application.

**Note**
Neurologists prescribing PBS-subsidised alemtuzumab must be registered with the Lemtrada monitoring program.
Special Pricing Arrangements apply.
No increase in the maximum quantity or number of units may be authorised.
No increase in the maximum number of repeats may be authorised.

**alemtuzumab 12 mg/1.2 mL injection, 1 x 1.2 mL vial**

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**ECULIZUMAB**

**Authority required**
Atypical haemolytic uraemic syndrome (aHUS)

**Treatment Phase:** Initial treatment 1 – New patient – Balance of Supply

**Clinical criteria:**
- Patient must have received PBS-subsidised initial supply of eculizumab for this condition, **AND**
- Patient must have ADAMTS-13 activity of greater than or equal to 10% on a blood sample, **AND**
- Patient must not receive more than 20 weeks supply under this restriction.

**Treatment criteria:**
- Must be treated by a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist, or, must be in consultation with a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist.
- ADAMTS-13 activity result must have been submitted to the Department of Human Services. In the case that a sample for ADAMTS-13 activity taken prior to plasma exchange or infusion was not available at the time of application for Initial Treatment 1 New Patient, ADAMTS-13 activity must have been measured 1–2 weeks following the last plasma exchange or infusion, and must have been submitted to the Department of Human Services within 27 days of commencement of eculizumab. The date and time that the sample for the ADAMTS-13 assay was collected, and the dates and times of the last, if any, plasma exchange or infusion that was undertaken in the two weeks prior to collection of the ADAMTS-13 assay must also have been provided to Department of Human Services.

**Note**
Serial haematological results (every 3 months while the patient is receiving treatment) must be provided with every subsequent application for treatment. This will assist DHS in the consideration of the patient’s eligibility for further PBS subsidised treatment
At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug for 4 weeks and up to 4 repeats, according to the specified dosage in the approved Product Information (PI).
Applications for treatment with eculizumab where the dose and dosing frequency exceeds that specified in the approved PI will not be approved.
Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Written applications for authority to prescribe must be submitted to Department of Human Services. Human Services will then contact the prescriber by telephone.

**eculizumab 300 mg/30 mL injection, 1 x 30 mL vial**

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**ECULIZUMAB**

**Authority required**
Atypical haemolytic uraemic syndrome (aHUS)

**Treatment Phase:** Initial treatment 1 – New patient

**Clinical criteria:**
- Patient must have active and progressing thrombotic microangiopathy (TMA), **AND**
- Patient must have ADAMTS-13 activity of greater than or equal to 10% on a blood sample taken prior to plasma exchange or infusion; or, if ADAMTS-13 activity was not collected prior to plasma exchange or infusion, patient must have platelet counts of greater than 30x10^9/L and a serum creatinine of greater than 150 mol/L, **AND**
- Patient must have a confirmed negative STEC (Shiga toxin-producing E.Coli) result if the patient has had diarrhoea in the preceding 14 days, **AND**
- Patient must have clinical features of active organ damage or impairment, **AND**
- Patient must not receive more than 4 weeks of treatment under this restriction.

**Treatment criteria:**
Must be treated by a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist, or, must be in consultation with a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist. Evidence of active and progressing TMA is defined by the following:

1. a platelet count of less than 150x10^9/L; and evidence of two of the following:
   i. presence of schistocytes on blood film;
   ii. low or absent haptoglobin;
   iii. lactate dehydrogenase (LDH) above normal range;

OR

2. tissue biopsy confirming TMA in patients who do not have evidence of platelet consumption and haemolysis; AND

3. evidence of at least one of the following clinical features of active TMA-related organ damage or impairment is defined as below:
   a. kidney impairment as demonstrated by one of the following:
      i. a decline in estimated Glomerular Filtration Rate (eGFR) of greater than 20% in a patient who has pre-existing kidney impairment; and/or
      ii. a serum creatinine (sCr) of greater than the upper limit of normal (ULN) in a patient who has no history of pre-existing kidney impairment; or
   b. a renal biopsy
   c. onset of TMA-related neurological impairment;
   d. onset of TMA-related cardiac impairment;
   e. onset of TMA-related gastrointestinal impairment;
   f. onset of TMA-related pulmonary impairment

The authority application must be in writing and must include:

1. A completed authority prescription form; and
2. A completed aHUS eculizumab Authority Application Supporting Information Form- Initial PBS-subsidised eculizumab treatment; and
3. A signed patient acknowledgement or an acknowledgement signed by a parent or authorised guardian, if applicable; and
4. A copy of a current Certificate of vaccination; and
5. A measurement of body weight at the time of application; and
6. The result of ADAMTS-13 activity on a blood sample taken prior to plasma exchange or infusion; the date and time that the sample for the ADAMTS-13 assay was collected, and the dates and times of any plasma exchanges or infusions that were undertaken in the two weeks prior to collection of the ADAMTS-13 assay; and
7. In the case that a sample for ADAMTS-13 assay was not collected prior to plasma exchange or infusion, measurement of ADAMTS-13 activity must be taken 1-2 weeks following the last plasma exchange or infusion. The ADAMTS-13 result must be submitted to the Department of Human Services within 27 days of commencement of eculizumab treatment in order for the patient to be considered as eligible for further PBS-subsidised eculizumab treatment, under Initial treatment 1-balance of supply; and
8. A confirmed negative STEC result if the patient has had diarrhoea in the preceding 14 days; and
9. Evidence of active and progressing TMA, including pathology results where relevant. Evidence of the onset of TMA-related neurological, cardiac, gastrointestinal or pulmonary impairment requires a supporting statement with clinical evidence in patient records. All tests must have been performed within one month of application; and
10. For all patients, a recent measurement of eGFR, platelets and two of either LDH, haptoglobin or schistocytes of no more than 1 week old at the time of application.

Note

Serial haematological results (every 3 months while the patient is receiving treatment) must be provided with every subsequent application for treatment. This will assist DHS in the consideration of the patient’s eligibility for further PBS-subsidised treatment.

At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug for four weeks of treatment, according to the specified dosage in the approved Product Information (PI). Applications for treatment with eculizumab where the dose and dosing frequency exceeds that specified in the approved PI will not be approved.

WARNING: Eculizumab increases the risk of meningococcal infections (septicaemia and/or meningitis)

> Vaccinate patients with a meningococcal vaccine at least 2 weeks prior to receiving the first dose of eculizumab;
> revaccinate according to current medical guidelines for vaccine use

> Patients less than 2 years of age and those who are treated with eculizumab less than 2 weeks after receiving a meningococcal vaccine must receive treatment with appropriate prophylactic antibiotics until 2 weeks after vaccination.

Monitor patients for early signs of meningococcal infections, evaluate immediately if infection is suspected, and treat with antibiotics if necessary.

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

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

Written applications for authority to prescribe must be submitted to Department of Human Services. Human Services will then contact the prescriber by telephone.
## ECULIZUMAB

**Authority required**

Atypical haemolytic uremic syndrome (aHUS)

**Treatment Phase:** Continuing treatment – New patient

**Clinical criteria:**

Patient must have received 24 weeks therapy under the initial restriction with PBS subsidised eculizumab for this condition, **AND**

Patient must have demonstrated on-going treatment response of PBS-subsidised eculizumab treatment for this condition, **AND**

Patient must not have experienced treatment failure with eculizumab including PBS-subsidised eculizumab for this condition, **AND**

Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

**Treatment criteria:**

Must be treated by a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist, or, must be in consultation with a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist.

A treatment response is defined as:

1. Normalisation of haematology as demonstrated by at least 2 of the following: platelet count, haptoglobin, and LDH; AND

2. One of the following:
   - An increase in eGFR of > 25% from baseline, where the baseline is the eGFR measurement immediately prior to commencing treatment with eculizumab or
   - An eGFR within +/- 25% from baseline; or
   - An avoidance of dialysis-dependence but worsening of kidney function with a reduction in eGFR 25% from baseline.

PBS-subsidised treatment with eculizumab will not be permitted if a patient has experienced treatment failure.

A treatment failure is defined as a patient who is:

1. Dialysis-dependent at the time of application and has failed to demonstrate significant resolution of extra-renal complications if originally presented; or

2. On dialysis and has been on dialysis for 4 months of the previous 6 months while receiving PBS-subsidised eculizumab and has failed to demonstrate significant resolution of extra-renal complications if originally presented.

Serial haematological results (every 3 months while the patient is receiving treatment) must be provided.

The authority application must be in writing and must include:

1. A completed authority prescription form; and
2. A completed aHUS eculizumab Authority Application Supporting Information Form for Continuing treatment; and
3. A copy of a current Certificate of vaccination; and
4. A measurement of body weight at the time of application; and
5. Evidence that the patient has had a treatment response including haematological results of no more than 1 week old at the time of application (platelet count, haptoglobin and LDH); and an eGFR level of no more than 1 week old at the time of application; and
6. Evidence that the patient has not experienced treatment failure, including a supporting statement with clinical evidence that the patient does not require dialysis, unless the indication for continuing eculizumab is severe extra-renal complications that have significantly improved; and
7. If the indication for continuing eculizumab is severe extra-renal complications, then a supporting statement with clinical evidence that any initial extra-renal complications of TMA have significantly improved is required.

**Authority required**

Atypical haemolytic uremic syndrome (aHUS)

**Treatment Phase:** Continuing treatment – beyond initial 48 weeks of treatment

**Clinical criteria:**

Patient must have received 48 weeks of treatment under Initial treatment-New patient, Initial treatment-Balance of supply and Continuing treatment-New patient with PBS-subsidised eculizumab for this condition, **AND**

Patient must have demonstrated on-going treatment response with PBS-subsidised eculizumab for this condition, **AND**

Patient must not have ever experienced treatment failure with eculizumab including PBS-subsidised eculizumab for this condition, **AND**

Patient must have a TMA-related cardiomyopathy as evidenced by left ventricular ejection fraction < 40%; OR

Patient must have severe TMA-related neurological impairment; OR

Patient must have severe TMA-related gastrointestinal impairment; OR

Patient must have severe TMA-related pulmonary impairment; OR

Patient must have grade 4 or 5 chronic kidney disease (eGFR of less than 30 ml/min), **AND**

Patient must not receive more than 24 weeks of treatment under this restriction.

**Treatment criteria:**

Must be treated by a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist, or, must be in consultation with a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist.

A treatment response is defined as:

1. Normalisation of haematology as demonstrated by at least 2 of the following: platelet count, haptoglobin, and LDH; AND
(2) One of the following:
a) An increase in eGFR of > 25% from baseline, where the baseline is the eGFR measurement immediately prior to commencing treatment with eculizumab or
b) an eGFR within +/- 25% from baseline; or
c) an avoidance of dialysis-dependence but worsening of kidney function with a reduction in eGFR 25% from baseline.

PBS-subsidised treatment with eculizumab will not be permitted if a patient has experienced treatment failure. A treatment failure is defined as a patient who is:
(1) dialysis-dependent at the time of application and has failed to demonstrate significant resolution of extra-renal complications if originally presented; or
(2) on dialysis and has been on dialysis for 4 months of the previous 6 months while receiving PBS-subsidised eculizumab and has failed to demonstrate significant resolution of extra-renal complications if originally presented.
Serial haematological results (every 3 months while the patient is receiving treatment) must be provided with every subsequent application for treatment. This will assist DHS in the consideration of the patient’s eligibility for further PBS subsidised treatment.

The authority application must be in writing and must include:
(1) A completed authority prescription form; and
(2) A completed aHUS eculizumab Authority Application Supporting Information Form for Initial treatment 2
(3) A copy of a current Certificate of vaccination; and
(4) A measurement of body weight at the time of application; and
(5) A supporting statement with clinical evidence of severe TMA have significantly improved; and
(6) Evidence that the patient has not experienced treatment failure, including a supporting statement with clinical evidence
(7) Evidence that the patient has not experienced treatment failure, including a supporting statement with clinical evidence that the patient does not require dialysis, unless the indication for continuing eculizumab is severe extra-renal complications that have significantly improved; and
(8) If the indication for continuing eculizumab is severe extra-renal complications, then a supporting statement with clinical evidence that any initial extra-renal complications of TMA have significantly improved is required.

Authority required
Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Initial treatment 2 – Recommencement of treatment after an initial 48-week period

Clinical criteria:
Patient must have demonstrated treatment response to previous 48 weeks of treatment with PBS-subsidised eculizumab for this condition, AND
Patient must not have ever experienced treatment failure with eculizumab including PBS-subsidised eculizumab for this condition, AND
Patient must have the following clinical conditions:(i) either significant haemolysis as measured by low/absent haptoglobin; or presence of schistocytes on the blood film; or lactate dehydrogenase (LDH) above normal;AND(ii) either platelet consumption as measured by either 25% decline from patient baseline or thrombocytopenia (platelet count <150 x 10^9/L);OR(iii) TMA-related organ impairment including on recent biopsy, AND
Patient must not receive more than 24 weeks of treatment under this restriction.

Treatment criteria:
Must be treated by a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist, or, must be in consultation with a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist.
A treatment response is defined as:
(1) Normalisation of haematology as demonstrated by at least 2 of the following: platelet count, haptoglobin, and LDH; AND
(2) One of the following:
a) An increase in eGFR of > 25% from baseline, where the baseline is the eGFR measurement immediately prior to commencing treatment with eculizumab or
b) an eGFR within +/- 25% from baseline; or
c) an avoidance of dialysis-dependence but worsening of kidney function with a reduction in eGFR 25% from baseline.
PBS-subsidised treatment with eculizumab will not be permitted if a patient has experienced treatment failure. A treatment failure is defined as a patient who is:
(1) dialysis-dependent at the time of application and has failed to demonstrate significant resolution of extra-renal complications if originally presented; or
(2) on dialysis and has been on dialysis for 4 months of the previous 6 months while receiving PBS-subsidised eculizumab and has failed to demonstrate significant resolution of extra-renal complications if originally presented.
Serial haematological results (every 3 months while the patient is receiving treatment) must be provided with every subsequent application for treatment. This will assist DHS in the consideration of the patient’s eligibility for further PBS subsidised treatment.

The authority application must be in writing and must include:
(1) A completed authority prescription form(s); and
(2) A completed aHUS eculizumab Authority Application Supporting Information Form for Initial treatment 2-
Recommencement of treatment after an initial 48-week period; and
(3) A signed patient acknowledgement or an acknowledgement signed by a parent or authorised guardian, if applicable; and
(4) A copy of a current Certificate of vaccination; and
(5) A measurement of body weight at the time of application; and
(6) A supporting statement with clinical evidence of TMA-related organ damage including current (within one week of application) haematological results (platelet count, haptoglobin and LDH), eGFR level, and, if applicable, on recent biopsy; and
(7) Evidence that the patient has had a treatment response to their previous treatment with eculizumab; and
(8) Evidence that the patient has not experienced treatment failure, including a supporting statement with clinical evidence that the patient does not require dialysis, unless the indication for continuing eculizumab is severe extra-renal complications that have significantly improved; and
(9) If the indication for continuing eculizumab is severe extra-renal complications, then a supporting statement with clinical evidence that any initial extra-renal complications of TMA have significantly improved is required.

Note
A raise in LDH alone is not a sufficient reason to re-commence eculizumab, but thrombocytopenia with one marker of haemolysis (such as raised LDH, presence of schistocytes, or low/absence of haptoglobin) is an accepted reason to consider re-commencement of eculizumab treatment.

Kidney transplantation/dialysis is not a contraindication to recommencement of eculizumab treatment.

Authority required
Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Continuing treatment – following recommencement of treatment after an initial 48-week period

Clinical criteria:
Patient must have received Initial treatment 2-recommencement of treatment after an initial 48-week period with PBS-subsidised eculizumab for this condition, AND
Patient must have demonstrated ongoing treatment response to the previous 24 weeks of PBS-subsidised eculizumab for this condition, AND
Patient must not have experienced treatment failure with eculizumab including PBS-subsidised eculizumab for this condition, AND
Patient must not receive more than 24 weeks of treatment under this restriction.

Treatment criteria:
Must be treated by a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist, or, must be in consultation with a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist.

A treatment response is defined as:
(1) Normalisation of haemoglobin as demonstrated by at least 2 of the following: platelet count, haptoglobin, and LDH; AND
(2) One of the following:
a) An increase in eGFR of > 25% from baseline, where the baseline is the eGFR measurement immediately prior to commencing treatment with eculizumab or
b) an eGFR within +/- 25% from baseline; or
c) an avoidance of dialysis-dependence but worsening of kidney function with a reduction in eGFR 25% from baseline.
PBS-subsidised treatment with eculizumab will not be permitted if a patient has experienced treatment failure. A treatment failure is defined as a patient who is:
(1) dialysis-dependent at the time of application and has failed to demonstrate significant resolution of extra-renal complications if originally presented; or
(2) on dialysis and has been on dialysis for 4 months of the previous 6 months while receiving PBS-subsidised eculizumab and has failed to demonstrate significant resolution of extra-renal complications if originally presented.
Serial haematological results (every 3 months while the patient is receiving treatment) must be provided with every subsequent application for treatment. This will assist DHS in the consideration of the patient’s eligibility for further PBS subsidised treatment.

The authority application must be in writing and must include:
(1) A completed authority prescription form; and
(2) A completed aHUS eculizumab Authority Application Supporting Information Form for Continuing treatment; and
(3) A copy of a current Certificate of vaccination; and
(4) A measurement of body weight at the time of application; and
(5) Evidence that the patient has had a treatment response including haematological results of no more than 1 week old at the time of application (platelet count, haptoglobin and LDH); and an eGFR level of no more than 1 week old at the time of application; and
(6) Evidence that the patient has not experienced treatment failure, including a supporting statement with clinical evidence that the patient does not require dialysis, unless the indication for continuing eculizumab is severe extra-renal complications that have significantly improved; and
(7) If the indication for continuing eculizumab is severe extra-renal complications, then a supporting statement with clinical evidence that any initial extra-renal complications of TMA have significantly improved is required.

Note
At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug for 4 weeks and up to 5 repeats, according to the specified dosage in the approved Product Information (PI).
Applications for treatment with eculizumab where the dose and dosing frequency exceeds that specified in the approved PI will not be approved.

Authority required
Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Initial 3 - Grandfather eculizumab patients

Clinical criteria:
Patient must have had documented history of active and progressing thrombotic microangiopathy (TMA), AND
Patient must have had documented an ADAMTS-13 activity level consistent with a diagnosis of aHUS, AND.
Patient must have received treatment with eculizumab for this condition prior to 1 December 2014, AND
Patient must have received treatment with eculizumab within the last 6 months at the time of application, AND
Patient must have demonstrated on-going treatment response as specified in the Continuing treatment New Patient criteria for PBS-subsidised treatment with eculizumab for this condition, if the patient has received adequate therapy in order to demonstrate response, AND
Patient must not have experienced treatment failure with eculizumab for this condition as specified in the Continuing treatment New Patient criteria for PBS-subsidised treatment with eculizumab for this condition, AND
Patient must have clinical features of active organ damage or impairment at the time of a diagnosis of aHUS episode that required treatment with eculizumab, AND
Patient must not receive more than 24 weeks of treatment under this restriction.

Treatment criteria:
Must be treated by a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist, or, must be in consultation with a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist.

Evidence of active and progressing TMA is defined by the following:
(1) a platelet count of less than 150x10^9/L; and evidence of two of the following:
(i) presence of schistocytes on blood film;
(ii) low or absent haptoglobin;
(iii) lactate dehydrogenase (LDH) above normal range;

(2) tissue biopsy confirming TMA in patients who do not have evidence of platelet consumption and haemolysis; AND
(3) evidence of at least one of the following clinical features of active TMA-related organ damage or impairment is defined as below:
(a) kidney impairment as demonstrated by one of the following:
(i) a decline in estimated Glomerular Filtration Rate (eGFR) of greater than 20% in a patient who has pre-existing kidney impairment; and/or
(ii) a serum creatinine (sCr) of greater than the upper limit of normal (ULN) in a patient who has no history of pre-existing kidney impairment; or
(iii) a sCr of greater than the age-appropriate ULN in paediatric patients; or
(iv) a renal biopsy
(b) onset of TMA-related neurological impairment;
(c) onset of TMA-related cardiac impairment;
(d) onset of TMA-related gastrointestinal impairment;
(e) onset of TMA-related pulmonary impairment

A treatment response is defined as:
(1) Normalisation of haematology as demonstrated by at least 2 of the following: platelet count, haptoglobin, and LDH; AND
(2) One of the following:
 a) An increase in eGFR of > 25% from baseline, where the baseline is the eGFR measurement immediately prior to commencing treatment with eculizumab or
 b) an eGFR within +/- 25% from baseline; or
 c) an avoidance of dialysis-dependence but worsening of kidney function with a reduction in eGFR 25% from baseline.

Patient must not receive more than 24 weeks of treatment under this restriction.

PBS-subsidised treatment with eculizumab will not be permitted if a patient has experienced treatment failure. A treatment failure is defined as a patient who is:
(1) dialysis-dependent at the time of application and has failed to demonstrate significant resolution of extra-renal complications if originally presented; or
(2) on dialysis and has been on dialysis for 4 months of the previous 6 months while receiving PBS-subsidised eculizumab and has failed to demonstrate significant resolution of extra-renal complications if originally presented.

The authority application must be in writing and must include:
(1) A completed authority prescription form; and
(2) A completed aHUS eculizumab Authority Application Supporting Information Form for initial PBS-subsidised eculizumab treatment; and
(3) A signed patient acknowledgement or an acknowledgement signed by a parent or authorised guardian, if applicable; and
(4) A copy of a current Certificate of vaccination; and
(5) A measurement of body weight at the time of application; and
(6) The result of ADAMTS-13 activity on a blood sample at the time this condition was diagnosed; and
(7) Evidence that the patient has previously received treatment with eculizumab for this condition within the last 6 months at the time of application; and
(8) Evidence that the patient has had a treatment response including haematological results of no more than 1 week old at the time of application (platelet count, haptoglobin and LDH); and an eGFR level of no more than 1 week old at the time of application; or clinical reasons to justify the commencing of treatment with PBS-subsidised eculizumab; and
(9) Evidence that the patient has not experienced treatment failure, including a supporting statement with clinical evidence that the patient does not require dialysis, unless the indication for continuing eculizumab is severe extra-renal complications that have significantly improved; and
(10) A confirmed negative STEC (Shiga toxin-producing E.Coli) result if available at the time of diagnosis; or evidence that the diagnosis was not associated with an infection; and
(11) Where available in the week prior to commencing eculizumab results demonstrating:
 a) a platelet count of less than 150 x10^9/L; and evidence of two of the following:
 i) presence of schistocytes on blood film;
(ii) low or absent haptoglobin;
(iii) lactate dehydrogenase (LDH) above normal range;
OR
(b) tissue biopsy confirming TMA in patients who do not have evidence of platelet consumption and haemolysis; AND
(c) evidence of at least one of the following clinical features of active TMA-related organ damage or impairment is defined as below:
(a) kidney impairment as demonstrated by one of the following:
(i) a decline in estimated Glomerular Filtration Rate (eGFR) of greater than 20% in a patient who has pre-existing kidney impairment; and/or
(ii) a serum creatinine (sCr) of greater than the upper limit of normal (ULN) in a patient who has no history of pre-existing kidney impairment; or
(iii) a sCr of greater than the age-appropriate ULN in paediatric patients; or
(iv) a renal biopsy
(b) onset of TMA-related neurological impairment;
(c) onset of TMA-related cardiac impairment;
(d) onset of TMA-related gastrointestinal impairment;
(e) onset of TMA-related pulmonary impairment; and
(12) Where available within one month prior to commencement of eculizumab, evidence of active and progressing TMA, including pathology results where relevant. Evidence of the onset of TMA-related neurological, cardiac, gastrointestinal or pulmonary impairment requires a supporting statement with clinical evidence in patient records.
Serial haematological results (every 3 months while the patient is receiving treatment) must be provided with every subsequent application for treatment. This will assist DHS in the consideration of the patient’s eligibility for further PBS subsidised treatment.

**Note**

**WARNING:** Eculizumab increases the risk of meningococcal infections (septicaemia and/or meningitis)
> Vaccinate patients with a meningococcal vaccine at least 2 weeks prior to receiving the first dose of eculizumab;
> revaccinate according to current medical guidelines for vaccine use
> Patients less than 2 years of age and those who are treated with eculizumab less than 2 weeks after receiving a meningococcal vaccine must receive treatment with appropriate prophylactic antibiotics until 2 weeks after vaccination.
Monitor patients

for early signs of meningococcal infections, evaluate immediately if infection is suspected, and treat with antibiotics if necessary.

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Written applications for authority to prescribe must be submitted to Department of Human Services. Human Services will then contact the prescriber by telephone.

eculizumab 300 mg/30 mL injection, 1 x 30 mL vial

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**EVEROLIMUS**

**Caution**

Careful monitoring of patients is mandatory.

**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

**everolimus 1 mg tablet, 60**

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**MYCOPHENOLATE**

**Caution**
Careful monitoring of patients is mandatory.

**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.

mycophenolate mofetil 1 g/5 mL oral liquid: powder for, 165 mL

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**MYCOPHENOLATE**

**Caution**
Careful monitoring of patients is mandatory.

**Authority required**
Prophylaxis of renal allograft rejection

**Clinical criteria:**
The treatment must be under the supervision and direction of a transplant unit.

**Authority required**
WHO Class III, IV or V lupus nephritis

**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.

**Note**
Management includes initiation, stabilisation and review of therapy as required.

mycophenolate mofetil 500 mg tablet, 50

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**MYCOPHENOLATE**

**Caution**
Careful monitoring of patients is mandatory.

**Authority required**
Prophylaxis of renal allograft rejection

**Clinical criteria:**
The treatment must be under the supervision and direction of a transplant unit.

**Authority required**
WHO Class III, IV or V lupus nephritis

**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.

**Note**
Management includes initiation, stabilisation and review of therapy as required.

mycophenolate 180 mg tablet: enteric, 120 tablets

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mycophenolate 360 mg tablet: enteric, 120 tablets

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**MYCOPHENOLATE**

**Caution**
Careful monitoring of patients is mandatory.

**Authority required**
Prophylaxis of renal allograft rejection

**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.

**Note**
For item codes 6208R and 1837Q, pharmaceutical benefits that have the form capsule 250 mg are equivalent for the purposes of substitution.
mycophenolate Capsule 250 mg, 50
1837Q

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mycophenolate mofetil 250 mg capsule, 100
6208R

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### NATAZILZUMAB

**Caution**
Progressive multifocal leukoencephalopathy has been reported with this drug.

**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

**Note**
Neurologists prescribing natalizumab under the PBS listing must be registered with the Tysabri Australian Prescribing Program.

Special Pricing Arrangements apply.

**natalizumab 300 mg/15 mL injection, 1 x 15 mL vial**
9624M

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### SIROLIMUS

**Caution**
Careful monitoring of patients is mandatory.

**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

**sirolimus 1 mg tablet, 100**
6436R

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**sirolimus 1 mg/mL oral liquid, 60 mL**
6437T

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**sirolimus 500 microgram tablet, 100**
9748C

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**Tumor necrosis factor alpha (TNF-) inhibitors**

**ADALIMUMAB**

**Authority required**
Severe active juvenile idiopathic arthritis

**Clinical criteria:**
Patient must have severe active juvenile idiopathic arthritis, AND
Patient must have received no prior PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition; OR
Patient must not have received PBS-subsidised treatment with adalimumab, etanercept or tocilizumab for this condition in the previous 12 months, AND
Patient must have demonstrated severe intolerance of, or toxicity due to, methotrexate; OR
Patient must have demonstrated failure to achieve an adequate response to 1 or more of the following treatment regimens: (i) oral or parenteral methotrexate at a dose of at least 20 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; or (ii) oral methotrexate at a dose of at least 10 mg per square metre weekly together with at least 1 other disease modifying anti-rheumatic drug (DMARD), alone or in combination with corticosteroids, for a minimum of 3 months, AND
Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:
Patient must be under 18 years of age and a parent or authorised guardian must have signed a patient acknowledgement.

Treatment criteria:
Must be treated by a paediatric rheumatologist; OR
Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.
For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.
Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.
Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis.
If treatment with methotrexate alone or in combination with another DMARD is contraindicated according to the relevant TGA approved Product Information, details must be provided at the time of application.
If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.
The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:
(a) an active joint count of at least 20 active (swollen and tender) joints; OR
(b) at least 4 active joints from the following list:
(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).
The joint count assessment must be performed preferably whilst still on DMARD treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.
The authority application must be made in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form; and
(3) an acknowledgement signed by a parent or authorised guardian.
At the time of authority application, medical practitioners must request the appropriate number of injections of appropriate strength, based on the weight of the patient, to provide sufficient for two doses. Up to a maximum of 3 repeats will be authorised.
If a patient fails to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle. A patient may re-trial adalimumab after a minimum of 12 months have elapsed between the date the last PBS-subsidised bDMARD was stopped and the date of the first application under a new treatment cycle.

Note
Use of alternative DMARDs in children is dependent on approval by the Therapeutic Goods Administration as age restrictions may apply.

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).

**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 12 months) or Initial 2 (change or recommencement of treatment after break of less than 12 months) – balance of supply

**Clinical criteria:**

Patient must have received insufficient adalimumab therapy under the Initial 1 (new patient or patient recommencing treatment after break of more than 12 months) restriction to complete 16 weeks treatment; OR

Patient must have received insufficient adalimumab therapy under the Initial 2 (change or recommencement of treatment after break of less than 12 months) restriction to complete 16 weeks treatment, AND

The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Treatment criteria:**

Must be treated by a paediatric rheumatologist; OR

Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

**Note**

Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:

Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826

HOBART TAS 7001

**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment

**Clinical criteria:**

Patient must have a documented history of severe active juvenile idiopathic arthritis, AND

Patient must have demonstrated an adequate response to treatment with adalimumab, AND

Patient must have received adalimumab as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment in this treatment cycle, AND

Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

**Treatment criteria:**

Must be treated by a rheumatologist; OR

Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

For the purposes of this restriction ‘biological disease modifying anti-rheumatic drug’ and ‘bDMARD’ mean adalimumab, etanercept or tocilizumab.

An adequate response to treatment is defined as:
(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:
(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurement of joint count submitted with the initial treatment application.

The authority application must be made in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners must request the appropriate number of injections of appropriate strength, based on the weight of the patient, to provide sufficient for two doses. Up to a maximum of 5 repeats will be authorised.

All applications for continuing treatment with adalimumab must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with adalimumab, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with adalimumab.

If a patient fails to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) they will not be eligible to receive further PBS-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
GPO Box 9826
HOBART TAS 7001

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, or on or after 1 April 2014, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 12 months may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.

(a) Initial treatment.

Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 12 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 12 months in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the...
date that course was ceased. 
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD. 
For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course. 
(b) Continuing treatment. 
Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. 
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply. 
Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. 
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD. 
(2) Swapping therapy. 
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 12 months. 
A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle. 
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction. 
To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing. 
(3) Baseline measurements to determine response. 
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement. 
(4) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy. 
A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 12 months, must requalify for treatment under the Initial 1 treatment restriction. 
(5) Withdrawal of treatment after sustained remission. 
Withdrawal of treatment with bDMARDs should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to the Department of Human Services at the time treatment is ceased. 

**Authority required** 
Severe active juvenile idiopathic arthritis 
Treatment Phase: 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

**adalimumab 20 mg/0.4 mL injection, 2 x 0.4 mL syringes** 

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ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

ETANERCEPT

**Authority required**
Severe active juvenile idiopathic arthritis

**Clinical criteria:**
- Patient must have severe active juvenile idiopathic arthritis, **AND**
- Patient must have received no prior PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition; **OR**
- Patient must not have received PBS-subsidised treatment with adalimumab, etanercept or tocilizumab for this condition in the previous 12 months, **AND**
- Patient must have demonstrated severe intolerance of, or toxicity due to, methotrexate; **OR**
- Patient must have demonstrated failure to achieve an adequate response to 1 or more of the following treatment regimens:
  - (i) oral or parenteral methotrexate at a dose of at least 20 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; or
  - (ii) oral methotrexate at a dose of at least 10 mg per square metre weekly together with at least 1 other disease modifying anti-rheumatic drug (DMARD), alone or in combination with corticosteroids, for a minimum of 3 months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**
- Patient must be under 18 years of age and a parent or authorised guardian must have signed a patient acknowledgement.
- **Treatment criteria:**
  - Must be treated by a paediatric rheumatologist; **OR**
  - Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.
  - For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.
  - Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.
  - Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis.
  - If treatment with methotrexate alone or in combination with another DMARD is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.
  - If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.
  - The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:
    - (a) an active joint count of at least 20 active (swollen and tender) joints; **OR**
    - (b) at least 4 active joints from the following list:
      - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
      - (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).
  - The joint count assessment must be performed preferably whilst still on DMARD treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.
- The authority application must be made in writing and must include:
  - (1) a completed authority prescription form; and
  - (2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form; and
  - (3) an acknowledgement signed by a parent or authorised guardian.
  - At the time of authority application, medical practitioners must request the appropriate number of injections 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.

**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).

Authority required
Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 12 months) or Initial 2 (change or recommencement of treatment after break of less than 12 months) – balance of supply

Clinical criteria:
- Patient must have received insufficient etanercept therapy under the Initial 1 (new patient or patient recommencing treatment after break of more than 12 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient etanercept therapy under the Initial 2 (change or recommencement of treatment after break of less than 12 months) restriction to complete 16 weeks treatment, and
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Treatment criteria:
- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Note
Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Authority required
Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment

**Clinical criteria:**
- Patient must have a documented history of severe active juvenile idiopathic arthritis, **AND**
- Patient must have demonstrated an adequate response to treatment with etanercept, **AND**
- Patient must have received etanercept as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment in this treatment cycle, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

**Treatment criteria:**
- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

For the purposes of this restriction ‘biological disease modifying anti-rheumatic drug’ and ‘bDMARD’ mean adalimumab, etanercept or tocilizumab.

An adequate response to treatment is defined as:
- (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
- (b) a reduction in the number of the following active joints, from at least 4, by at least 50%:
  - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
  - (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurement of joint count submitted with the initial treatment application.

The authority application must be made in writing and must include:
- (1) a completed authority prescription form; and
- (2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners must request the appropriate number of injections to provide sufficient for four weeks of treatment. Up to a maximum of 5 repeats will be authorised.

All applications for continuing treatment with etanercept must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with etanercept, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with etanercept.

If a patient fails to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle.

**Note**

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

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

Applications for authority to prescribe should be forwarded to:
- Department of Human Services
- Prior Written Approval of Complex Drugs
- Reply Paid 9826
- GPO Box 9826

HOBART TAS 7001

**TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient who has severe active juvenile idiopathic arthritis. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.

From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:
- (i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and
- (ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised biological therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 12 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 12 months may commence a further course of treatment within the same treatment cycle.
A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 12 months (Initial 1); or

(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or

(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 12 months in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 12 months.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.

(4) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 12 months, must requalify for treatment under the Initial 1 treatment restriction.

(5) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with bDMARDs should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to the Department of Human Services at the time treatment is ceased.

**Authority required**

Severe active juvenile idiopathic arthritis

**Treatment Phase:** Continuing treatment – balance of supply

**Clinical criteria:**

Patient must have received insufficient 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 Injection 50 mg in 1 mL single use auto-injector, 4, 1

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ETANERCEPT Injections 50 mg in 1 mL single use pre-filled syringes, 4, 1

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

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**INFLIXIMAB**

**Authority required**

Acute severe ulcerative colitis

**Clinical criteria:**

Patient must have received an infusion of infliximab for the treatment of this condition as a hospital inpatient no more than two weeks prior to the date of the authority application, AND

Patient must be an adult aged 18 years or older, and prior to initiation of infliximab treatment in hospital must have been experiencing six or more bloody stools per day, plus at least one of the following: (i) Temperature greater than 37.8 degrees Celsius; (ii) Pulse rate greater than 90 beats per minute; (iii) Haemoglobin less than 105 g/L; (iv) Erythrocyte sedimentation rate greater than 30 mm/h; OR

Patient must be a child aged 6 to 17 years inclusive, and prior to initiation of infliximab treatment in hospital must have had a Paediatric Ulcerative Colitis Activity Index (PUCAI) greater than or equal to 65, with the diagnosis confirmed by a gastroenterologist, or a consultant physician as specified below, AND

Patient must have failed to achieve an adequate response to at least 72 hours treatment with intravenous corticosteroids prior to initiation of infliximab treatment in hospital.

**Population criteria:**

Patient must be 6 years of age or older.

**Treatment criteria:**

Must be treated by a gastroenterologist; OR

Must be treated by a consultant physician [internal medicine specialising in gastroenterology, or general medicine specialising in gastroenterology].

For adults aged 18 years or older, failure to achieve an adequate response to intravenous corticosteroid treatment is defined by the Oxford criteria where:

(i) If assessed on day 3, patients pass 8 or more stools per day or 3 or more stools per day with a C-reactive protein (CRP) greater than 45 mg/L

(ii) If assessed on day 7, patients pass 3 or more stools per day with visible blood.

For children aged 6 to 17 years, failure to achieve an adequate response to intravenous corticosteroids means a PUCAI score greater than 45 at 72 hours.

At the time of authority application, prescribers should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg.

Before administering infliximab to a child aged 6 to 17 years, the treating clinician must have consulted with a paediatric gastroenterologist or with an institution experienced in performance of paediatric colectomy. The name of the specialist or institution must be included in the patient's medical records.

Evidence that the patient meets the PBS restriction criteria must be recorded in the patient’s medical records.

**Note**

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

**INFLIXIMAB**

**Authority required**

**infliximab 100 mg injection, 1 x 100 mg vial**

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Initial treatment of Crohn disease in a paediatric patient.

Initial PBS-subsidised treatment by a gastroenterologist, paediatrician or consultant physician as specified in the NOTE below, of a patient aged 6 to 17 years inclusive with moderate to severe refractory Crohn disease who satisfies the following criteria:

(a) has confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or consultant physician as specified in the NOTE below; and
(b) whose parent or authorised guardian has signed a patient acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and
(c) has failed to achieve an adequate response to 2 of the following 3 conventional prior therapies including:
(i) a tapered course of steroids, starting at a dose of at least 1 mg per kg or 40 mg (whichever is the lesser) prednisolone (or equivalent), over a 6 week period;
(ii) an 8 week course of enteral nutrition;
(iii) immunosuppressive therapy including:
— azathioprine at a dose of at least 2 mg per kg daily for 3 or more months; or
— 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months; or
— methotrexate at a dose of at least 10 mg per square metre weekly for 3 or more months.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of the accepted toxicities including severity can be found on the Medicare Australia website (www.medicareaustralia.gov.au).

The following initiation criterion indicates failure to achieve an adequate response and must be demonstrated in all patients at the time of the application:

(a) severity of disease activity which results in a Paediatric Crohn Disease Activity Index (PCDAI) Score greater than or equal to 30 as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

(b) The most recent PCDAI assessment must be no more than 1 month old at the time of application.

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and
(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) the completed current Paediatric Crohn Disease Activity Index (PCDAI) calculation sheet including the date of assessment of the patient's condition; and
(ii) details of previous systemic drug therapy [dosage, date of commencement and duration of therapy], or dates of enteral nutrition; and
(iii) the signed patient acknowledgement.

A maximum quantity and number of repeats to provide for an initial course of infliximab consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of 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 treatment 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 (general 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.
### 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, no applications for increased repeats will be authorised.

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. An assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose. 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 continuation of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment

**Authority required**

Initial 3 (grandfather)

Initial PBS-subsidised treatment of complex refractory FISTULISING CROHN DISEASE in a patient who has previously received non-PBS-subsidised therapy with infliximab.

Initial PBS-subsidised supply for continuing treatment with infliximab by a gastroenterologist, a consultant physician as specified in the NOTE below, or other consultant physician in consultation with a gastroenterologist of a patient who satisfies the following criteria:

(a) has a documented history of complex refractory fistulising Crohn disease and was receiving treatment with infliximab prior to 1 March 2010; and

(b) had a draining enterocutaneous or rectovaginal fistula(e) prior to commencing treatment with infliximab; and

(c) has signed a patient acknowledgement indicating that they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criteria for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and

(d) is receiving treatment with infliximab at the time of application; and

(e) has demonstrated or sustained an adequate response to treatment with infliximab.

**NOTE:** Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

An adequate response to infliximab treatment is defined as:

(a) a decrease from baseline in the number of open draining fistulae of greater than or equal to 50%; and/or

(b) a marked reduction in drainage of all fistula(e) from baseline, together with less pain and induration as reported by the patient.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Fistulising Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
  (i) a completed current and baseline Fistula Assessment form including the date of assessment of the patient's condition; and
  (ii) a signed patient acknowledgement.

The current fistula assessment must be no more than 1 month old at the time of application.

The baseline fistula assessment must be from immediately prior to commencing treatment with infliximab.

An assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criteria.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with infliximab.

Applications for continuing treatment must be made in writing and must include:

(a) authority prescription form; and

(b) 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) completed current and baseline 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 a continuing course of treatment with 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.

An assessment of the patient's response to this continuing course of treatment must be made up to 12 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 4 weeks from the date that course was ceased. 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 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) authority prescription form; and

(b) 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) 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).
 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

TREATMENT OF COMPLEX REFRACTORY FISTULISING CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab and infliximab for patients with complex refractory fistulising Crohn disease. Where the term ‘tumour necrosis factor (TNF) alfa antagonist’ appears in the following NOTES and restrictions, it refers to adalimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 2 TNF-alfa antagonists at any 1 time.

From 1 April 2011, under the PBS, all patients will be able to commence a treatment cycle where they may trial each PBS-subsidised TNF-alfa antagonist without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a TNF-alfa antagonist while they continue to show a response to therapy.

A patient who received PBS-subsidised TNF-alfa antagonist treatment prior to 1 April 2011 is considered to be in their first cycle as of 1 April 2011.

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 alternate 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 course 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.

infliximab 100 mg injection, 1 x 100 mg vial

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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:
(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 sensitivity, associated with phototherapy, methotrexate, cyclosporin and acitretin, can be found on the

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.

Approval will be based on the PASI assessment of response to this course of treatment.

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.

(c) The most recent PASI assessment must be no more than 1 month old at the time of application.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient’s condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; and

(iii) the signed patient and prescriber acknowledgements.

A maximum of 22 weeks of treatment with infliximab will be authorised under this restriction.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 22 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period beyond 22 weeks.

A PASI assessment of the patient’s response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline

**Authority required**

**Initial or re-Treatment [Initial 2, Face, hand, foot (Received prior biological agent under PBS)]**

Treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over who:
(a) have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot; and
(b) have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle; and
(c) have not failed PBS-subsidised therapy with infliximab for the treatment of this condition in the current Treatment Cycle. Applications for authorisation must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and
(ii) details of prior biological treatment, including dosage, date and duration of treatment.
Applications for patients who have demonstrated a response to PBS-subsidised infliximab treatment within this Treatment Cycle and who wish to re-commence infliximab treatment within the same Cycle following a break in therapy, will only be approved where evidence of the patient's response to their most recent course of PBS-subsidised infliximab treatment has been submitted to Medicare Australia within 1 month of cessation of treatment.
A maximum of 22 weeks of treatment with infliximab will be authorised under this restriction.
At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.
Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 22 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period beyond 22 weeks.
A PASI assessment of the patient's response to this course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.
It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment.
The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline. Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may re-commence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle
Authority required
Continuing treatment (Face, hand, foot)
Continuing PBS-subsidised treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over:
(a) 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

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 cease 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

Schedule of Pharmaceutical Benefits 721

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS
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 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.

No applications for increased repeats will be authorised.

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### INFLIXIMAB

**Authority required**
 Moderate to severe ulcerative colitis

**Treatment Phase: Initial treatment (new patient)**

**Clinical criteria:**
- Patient must have failed to achieve an adequate response to a 5-aminosalicylate oral preparation in a standard dose for induction of remission for 3 or more months or have intolerance necessitating permanent treatment withdrawal, **AND**
- Patient must have failed to achieve an adequate response to azathioprine at a dose of at least 2 mg per kg daily for 3 or more months or have intolerance necessitating permanent treatment withdrawal; **OR**
- Patient must have failed to achieve an adequate response to 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months or have intolerance necessitating permanent treatment withdrawal; **OR**
- Patient must have failed to achieve an adequate response to a tapered course of oral steroids, starting at a dose of at least 40 mg (for a child, 1 to 2 mg/kg up to 40 mg) prednisolone (or equivalent), over a 6 week period or have intolerance necessitating permanent treatment withdrawal, **AND**
- Patient must have a Mayo clinic score greater than or equal to 6 if an adult patient; **OR**

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Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score); OR

Patient must have a Paediatric Ulcerative Colitis Activity Index (PUCAI) Score greater than or equal to 30 if aged 6 to 17 years.

**Population criteria:**

Patient must be 6 years of age or older.

**Treatment criteria:**

Must be treated by a gastroenterologist (code 87) or a consultant physician [general medicine specialising in gastroenterology (code 81)] or a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR

Must be treated by a paediatrician or specialist paediatric gastroenterologist if aged between 6 to 17 years.

Applications for authorisation of initial treatment must be in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Ulcerative Colitis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current Mayo clinic or partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) calculation sheet including the date of assessment of the patient’s condition; and

(ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and

(iii) the signed patient acknowledgement.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment. The most recent Mayo clinic, partial Mayo clinic or PUCAI score must be no more than 1 month old at the time of application.

Patients who fail to achieve a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1, or a PUCAI score less than 10 within the first 12 weeks of receiving this drug for ulcerative colitis, or have failed to maintain a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1, or have failed to maintain a PUCAI score less than 10 (if aged 6 to 17 years) with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug.

A partial Mayo clinic or PUCAI assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

The patient or guardian (required if patient aged 6 to 17 years) must have signed a patient acknowledgement indicating they understand and acknowledge that the PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application. If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application.

Patients may qualify for PBS-subsidised treatment under this restriction once only.

**Note**

Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Department of Human Services website at www.humanservices.gov.au

**Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Initial PBS-subsidised treatment of moderate to severe ulcerative colitis in a patient who has previously received non-PBS-subsidised therapy with this drug (grandfather)

**Clinical criteria:**

Patient must have been receiving treatment with this drug prior to 1 December 2014, AND

Patient must have had a Mayo clinic score greater than or equal to 6 prior to commencing treatment with this drug; OR

Patient must have had a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores were both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo score) prior to commencing treatment with this drug; OR

Patient must have had a Paediatric Ulcerative Colitis Activity Index (PUCAI) Score greater than or equal to 30 prior to commencing treatment with this drug; OR

Patient must have a documented history of moderate to severe refractory ulcerative colitis prior to having commenced treatment with this drug where a Mayo clinic, partial Mayo clinic or PUCAI baseline assessment is not available, AND

Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug; OR

Patient must have demonstrated or sustained an adequate response to treatment by having a Paediatric Ulcerative Colitis Activity Index (PUCAI) score less than 10 while receiving treatment with this drug if aged 6 to 17 years.

**Population criteria:**

Patient must be 6 years of age or older.

**Treatment criteria:**

Must be treated by a gastroenterologist (code 87) or a consultant physician [general medicine specialising in gastroenterology (code 81)] or a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR

Must be treated by a paediatrician or specialist paediatric gastroenterologist if aged between 6 to 17 years.

Applications for authorisation of initial treatment must be in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Ulcerative Colitis PBS Authority Application - Supporting Information Form which includes the following:
The current Mayo clinic or partial Mayo clinic or PUCAI assessment must be no more than 1 month old at the time of application. The baseline assessment must be from immediately prior to commencing treatment with this drug. Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain the response.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to be sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised. No applications for increased repeats will be authorised. The patient or guardian (required if patient aged 6 to 17 years) must have signed a patient acknowledgement indicating they understand and acknowledge that the PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment.

Patients may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria.

Note
Where a baseline assessment is not available, please call the Department of Human Services on 1800 700 270 to discuss (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (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
Moderate to severe ulcerative colitis
Treatment Phase: Balance of supply
Clinical criteria:
Patient must have received insufficient therapy with this drug under the Initial treatment (new patient) restriction to complete the 3 doses (i.e. the initial infusion regimen at weeks 0, 2 and 6 weeks); OR
Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks of treatment; OR
Patient must have received insufficient therapy with this drug to complete 24 weeks of treatment under the Initial PBS-subsidised treatment restriction for patients who had previously received non-PBS subsidised treatment (Grandfathered patient), AND
The treatment must provide no more than the balance of up to 3 doses (new patients) or 2 repeats (Continuing patients or Grandfathered patients).

Population criteria:
Patient must be 6 years of age or older.

Treatment criteria:
Must be treated by a gastroenterologist (code 87) or a consultant physician [internal medicine specialising in gastroenterology (code 81)] or a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
Must be treated by a paediatrician or specialist paediatric gastroenterologist if aged between 6 to 17 years.

Note
Authority approval for sufficient therapy to complete a maximum of 3 initial doses or 2 repeats may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written applications for authority approval for sufficient therapy to complete a maximum of 3 initial doses or 2 repeats should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826

HOBART TAS 7001

Authority required
Moderate to severe ulcerative colitis
Treatment Phase: Continuing treatment
Clinical criteria:
Patient must have previously been issued with an authority prescription for this drug for this condition, AND
Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug; OR
Patient must have demonstrated or sustained an adequate response to treatment by having a Paediatric Ulcerative Colitis Activity Index (PUCAI) score less than 10 while receiving treatment with this drug if aged 6 to 17 years.

**Treatment criteria:**
Must be treated by a gastroenterologist (code 87) or a consultant physician [internal medicine specialising in gastroenterology (code 81)] or a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
Must be treated by a paediatrician or specialist paediatric gastroenterologist if aged between 6 to 17 years.

Patients who have failed to maintain a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1, or, patients who have failed to maintain a PUCAl score less than 10 (if aged 6 to 17 years) with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain the response.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised. No applications for increased repeats will be authorised.

**Note**
Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826

HOBART TAS 7001
Special Pricing Arrangements apply.

**infliximab 100 mg injection, 1 x 100 mg vial**

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**INFLIXIMAB**

**Authority required**
Severe active rheumatoid arthritis

**Treatment Phase:** Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months)

**Clinical criteria:**
Patient must have severe active rheumatoid arthritis, **AND**
Patient must have received no PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition in the previous 24 months, **AND**
Patient must have not failed previous PBS-subsidised treatment with infliximab for this condition, and have not already failed, or ceased to respond to, PBS-subsidised bDMARD treatment for this condition **5 times**, **AND**
Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR
Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR
Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above, must include at least 3 months continuous treatment with each of at least 2 DMARDs, with one or more of the following DMARDs being used in place of the DMARDs which are contraindicated or not tolerated: (i) azathioprine at a dose of at least 1 mg/kg per day; and/or (ii) cyclosporin at a dose of at least 2 mg/kg/day; and/or (iii) sodium aurothiomalate at a dose of 50 mg weekly, **AND**
Patient must not receive more than 22 weeks of treatment under this restriction, **AND**

The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

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

**Treatment criteria:**
Must be treated by a rheumatologist; OR
Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.
For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab or tocilizumab.
If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable. The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.
If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application including severity.
The authority application must be made in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form; and
(3) a signed patient acknowledgement.

Assessment of a patient's response to an initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted no later than 1 month from the date of completion of this initial course of treatment.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.
Applications for a patient who has received PBS-subsidised treatment with infliximab and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised infliximab treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised infliximab treatment was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.
Where the most recent course of PBS-subsidised infliximab treatment was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.
If a patient fails to demonstrate a response to treatment with infliximab under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.
The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:
an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either
(a) a total active joint count of at least 20 active (swollen and tender) joints; or
(b) at least 4 active joints from the following list of major joints:
(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).
The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.
If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.
Where the baseline joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP is provided with the initial application, the same marker will be used to determine response.

Note
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.
Special Pricing Arrangements apply.

Authority required
Severe active rheumatoid arthritis
Treatment Phase: Initial treatment - Initial 2 (change or re-commencement of treatment after break of less than 24 months).
Clinical criteria:
Patient must have a documented history of severe active rheumatoid arthritis, AND
Patient must have received prior PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition and are eligible to receive further bDMARD therapy, **AND**

Patient must not receive more than 22 weeks of treatment under this restriction, **AND**

The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

### Population Criteria:

Patient must be aged 18 years or older.

### Treatment Criteria:

Must be treated by a rheumatologist; **OR**

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab or tocilizumab.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners should request the appropriate number of vials to provide sufficient drug, based on the weight of the patient, for single infusion at a dose of 3 mg per kg. Up to a maximum of 3 repeats will be authorised.

Applications for a patient who has received PBS-subsidised treatment with infliximab and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised infliximab treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised infliximab treatment was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised infliximab treatment was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

If a patient fails to demonstrate a response to a treatment with infliximab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD.

An adequate response to treatment is defined as:

- an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;
- **AND** either of the following:
  - (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
  - (b) a reduction in the number of the following active joints, from at least 4, by at least 50%:
    - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
    - (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

### Authority Required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months) or Initial 2 (change or recommencement of treatment after break of less than 24 months) – balance of supply.

### Clinical Criteria:

Patient must have received insufficient infliximab therapy under the Initial 1 (new patient or patient recommencing treatment after break of more than 24 months) restriction to complete 22 weeks treatment; **OR**

Patient must have received insufficient infliximab therapy under the Initial 2 (change or recommencement of treatment after break of less than 24 months) restriction to complete 22 weeks treatment, **AND**

The treatment must provide no more than the balance of up to 22 weeks treatment available under the above restrictions.

### Treatment Criteria:

Must be treated by a rheumatologist; **OR**

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

### Note

Authority approval for sufficient therapy to complete a maximum of 22 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 22 weeks of treatment should be forwarded to:

Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826

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### Authority Required
Severe active rheumatoid arthritis
Treatment Phase: Continuing treatment.

Clinical criteria:
Patient must have a documented history of severe active rheumatoid arthritis, AND
Patient must have demonstrated an adequate response to treatment with infliximab, AND
Patient must have received infliximab as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment, AND
Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction, AND
The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

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

Treatment criteria:
Must be treated by a rheumatologist; OR
Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab or tocilizumab.

An adequate response to treatment is defined as:
an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;
AND either of the following:
(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:
   (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
   (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners should request the appropriate number of vials to provide sufficient drug, based on the weight of the patient, for single infusion at a dose of 3 mg per kg. Up to a maximum of 2 repeats will be authorised.

All applications for continuing treatment with infliximab must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with infliximab, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

If a patient fails to demonstrate a response to treatment with infliximab under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

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

HOBART TAS 7001

TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab) and the T-cell co-stimulation modulator (abatacept).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:
a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis. For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-α antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or

(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or

(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or

(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy. Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab and tocilizumab, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course. Abatacept patients:

Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:

A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction. Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing).
with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug. 

Abatacept patients:
Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.
In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.
To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Authority required
Severe active rheumatoid arthritis
Treatment Phase: Continuing Treatment – balance of supply.
Clinical criteria:
Patient must have received insufficient infliximab therapy under the Continuing Treatment restriction to complete 24 weeks treatment, AND
The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.
Treatment criteria:
Must be treated by a rheumatologist; OR
Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Note
Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

infliximab 100 mg injection, 1 x 100 mg vial

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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

For details on the appropriate minimum exercise program that will be accepted for the purposes of administering this restriction, please refer to the Department of Human Services website at www.humanservices.gov.au

**Authority required**
- Ankylosing spondylitis
- Treatment Phase: Initial 2 (change or recommencement for all patients)

**Clinical criteria:**
- Patient must have a documented history of active ankylosing spondylitis, **AND**
- Patient must have received prior PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition in this treatment cycle, **AND**
- Patient must not have failed PBS-subsidised therapy with this drug for this condition in the current treatment cycle, **AND**
- Patient must be eligible to receive further bDMARD therapy.

**Population criteria:**
- Patient must be an adult.

**Treatment criteria:**
- Must be treated by a rheumatologist.

Where the most recent course of PBS-subsidised bDMARD treatment was approved under either of the initial treatment restrictions (i.e. for patients with no prior PBS-subsidised bDMARD therapy or, under this restriction, for patients who have...
received previous PBS-subsidised bDMARD therapy) the patient must have been assessed for response to that course following a minimum of 12 weeks of treatment. These assessments must be provided to the Department of Human Services no later than 4 weeks from the date the course was ceased. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, patients must have been assessed for response, and the assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and
(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form.

A maximum of 18 weeks of treatment with this drug will be approved under this criterion.

At the time of authority application, the doctor should request the appropriate number of vials, based on the weight of the patient, to provide for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.

Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised bDMARD was approved in this cycle and the date of the first application under a new cycle.

**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

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**Authority required**

Ankylosing spondylitis

Treatment Phase: Continuing treatment

**Clinical criteria:**

Patient must have a documented history of active ankylosing spondylitis, **AND**

Patient must have received this drug as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment in this treatment cycle, **AND**

Patient must have demonstrated an adequate response to treatment with this drug.

**Population criteria:**

Patient must be an adult.

**Treatment criteria:**

Must be treated by a rheumatologist.

An adequate response is defined as an improvement from baseline of at least 2 of the BASDAI and 1 of the following:

(a) an ESR measurement no greater than 25 mm per hour; or
(b) a CRP measurement no greater than 10 mg per L; or
(c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and supplied in all subsequent continuing treatment applications.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and
(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form.

All measurements provided must be no more than 1 month old at the time of application.

A maximum of 24 weeks of treatment with this drug will be authorised under this criterion.
At the time of authority application, the doctor should request the appropriate number of vials, based on the weight of the patient, to provide for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.

All applications for continuing treatment with this drug must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment following an initial treatment course it must be made following a minimum of 12 weeks of treatment with this drug. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised bDMARD was approved in this cycle and the date of the first application under a new cycle.

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

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

Applications for authority to prescribe should be forwarded to:
Department of Human Services
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GPO Box 9826

HOBART TAS 7001

TREATMENT OF ADULT PATIENTS WITH ACTIVEankylosing SPONDYLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, certolizumab pegol, etanercept, golimumab and infliximab for adult patients with active ankylosing spondylitis. Where the term ‘bDMARD’ appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab and infliximab 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 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...
(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**

Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:

- Department of Human Services
- Prior Written Approval of Complex Drugs
- Reply Paid 9826
- GPO Box 9826

HOBART TAS 7001

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**INFLIXIMAB**

**Authority required**

Severe psoriatic arthritis
Treatment Phase: Initial treatment – Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more).

**Clinical criteria:**

- Patient must have severe active psoriatic arthritis, **AND**
- Patient must have received no prior PBS-subsidised treatment with a biological agent for this condition; OR
Patient must have received no PBS-subsidised treatment with a biological agent for at least 5 years if they have previously received PBS-subsidised treatment with a biological agent for this condition, **AND**
Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months, **AND**
Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; **OR**
Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months, **AND**
Patient must not receive more than 22 weeks of treatment under this restriction.

**Population criteria:**
Patient must be an adult.

**Treatment criteria:**
Must be treated by a rheumatologist; **OR**
Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab or infliximab.

Where treatment with methotrexate, sulfasalazine or leflunomide is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.
Where intolerance to treatment with methotrexate, sulfasalazine or leflunomide developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:
-an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; and
either
(a) an active joint count of at least 20 active (swollen and tender) joints; or
(b) at least 4 active joints from the following list of major joints:
(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).
If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form; and
(3) a signed patient acknowledgement.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats may be authorised.

**Note**
Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 3 months treatment with methotrexate and 3 months treatment with sulfasalazine or leflunomide can be found on the Department of Human Services website (www.humanservices.gov.au)

**Authority required**
Severe psoriatic arthritis
Treatment Phase: Initial treatment – Initial 2 (change or recommencement of treatment)

**Clinical criteria:**
Patient must have a documented history of severe active psoriatic arthritis, **AND**
Patient must have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle, **AND**
Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological agents within this Treatment Cycle, **AND**
Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug during the current Treatment Cycle, **AND**
Patient must not receive more than 22 weeks of treatment under this restriction.

**Population criteria:**
Patient must be an adult.

**Treatment criteria:**
Must be treated by a rheumatologist; **OR**
Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.
For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab or infliximab.
The authority application must be made in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form.
At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats may be authorised.

Applications for a patient who has previously received PBS-subsidised treatment with this drug within this Treatment Cycle and who wishes to recommence therapy with this drug within this same Cycle, must be accompanied by evidence of a response to the patient’s most recent course of PBS-subsidised treatment with this drug.

Where the most recent course of PBS-subsidised treatment was approved under either of the initial treatment restrictions (i.e. for patients with no prior PBS-subsidised biological therapy or, under this restriction, for patients who have received previous PBS-subsidised biological therapy), the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must have been submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment submitted no later than 4 weeks from the date that course was ceased.

Where a response assessment was not submitted within these timeframes, the patient will be deemed to have failed to respond to treatment.

An adequate response to treatment is defined as:

- an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and
- either of the following:
  - (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
  - (b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:
    - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
    - (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Note

The assessment of the patient’s response to this initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted to the Department of Human Services no later than 4 weeks from the cessation of the treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Authority required

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more) or Initial 2 (change or recommencement of treatment) - balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug under the Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more) restriction to complete 22 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement of treatment) restriction to complete 22 weeks treatment, AND

The treatment must provide no more than the balance of up to 22 weeks treatment available under the above restrictions.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Note

Authority approval for sufficient therapy to complete a maximum of 22 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 22 weeks of treatment should be forwarded to:

Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Authority required

Severe psoriatic arthritis

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have a documented history of severe active psoriatic arthritis, AND
- Patient must have received this drug as their most recent course of PBS-subsidised treatment with a biological agent for this condition in the current Treatment Cycle, AND
- Patient must demonstrate, at the time of application, an adequate response to treatment with this drug, AND
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

Population criteria:

- Patient must be an adult.

Treatment criteria:
Must be treated by a rheumatologist; OR
Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab or infliximab.

An adequate response to treatment is defined as:
an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:
(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:
   (i) elbow, wrist and/or ankle (assessed as swollen and tender); and/or
   (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and
   limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial

treatment application must be provided for all subsequent continuing treatment applications.

All applications for continuing treatment with this drug must include a measurement of response to the most recent course of PBS-subsidised therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with the initial treatment course.

Where a response assessment is not submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

The authority application must be made in writing and must include:

1. a completed authority prescription form; and
2. a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats may be authorised.

Note
Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

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

Prescribing information (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 SEVERE ACTIVE PSORIATIC ARTHRITIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, certolizumab pegol, etanercept, golimumab and infliximab for adult patients with severe active psoriatic arthritis.

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological agents at any 1 time.

Where the term 'biological agents' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab and infliximab only.

Patients receiving PBS-subsidised treatment for psoriatic arthritis are able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy. Following demonstration of response to initial treatment, these biological agents are available under the PBS for continuing treatment as set out in the continuing treatment restriction for each agent.

Once patients have either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological therapy before they are eligible to commence another Cycle [further details are under '(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' below].

The duration of the break in therapy will be measured from the date the last approval for PBS-subsidised treatment was granted in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Cycle.

Within the same Cycle, patients are not allowed to fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for any biological agent, they must change to an alternate agent which they have not previously failed, if they wish to continue PBS-subsidised biological treatment.

Patients for whom a break in PBS-subsidised therapy of less than 5 years has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.
Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle. There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe active psoriatic arthritis.

(1) Initial treatment.

Applications for initial treatment should be made where:
(i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); and
(ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; and
(iii) patients wish to re-commence treatment with a specific biological agent following a break in PBS-subsidised therapy with that specific agent (Initial 2).

All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept and golimumab, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), and 22 weeks of therapy for infliximab. It is recommended that patients be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological agent supply.

Patients must be assessed for response to any course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

Grandfather patients - certolizumab pegol only.

For patients who commenced treatment with certolizumab pegol for psoriatic arthritis prior to 1 April 2015, applications for initial PBS-subsidised treatment as continuing therapy may be made under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with any biological agent prior to PBS listing of that agent.

Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment for all agents. Approval will be based on the criteria included in the relevant restriction.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological agent, patients may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. Patients are eligible to receive continuing biological treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

Patients must be assessed for response to a course of continuing therapy, and the assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

(3) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate biological agent without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements.

Patients may swap to an alternate biological agent at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological agent at the time of the application or not.

Within a Treatment Cycle patients may alternate between therapy with any biological agent of their choice (1 at a time) providing:
(i) they have not received PBS-subsidised treatment with that particular biological agent previously; or
(ii) they have demonstrated an adequate response to that particular biological agent if they have previously trialled it on the PBS; and
(iii) they have not previously failed to respond to treatment 3 times in this Treatment Cycle.

To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the biological agent the patient is ceasing.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the indices of disease severity submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment application is submitted within a treatment Cycle and these revised baseline measurements will be used to assess response.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

Patients who wish to trial a second or subsequent treatment Cycle following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment with respect to both the indices of disease severity. Patients must have received treatment with methotrexate and sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured.

Authority required
Severe psoriatic arthritis
Treatment Phase: Continuing treatment - balance of supply

Clinical criteria:
Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, AND
The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Treatment criteria:**
Must be treated by a rheumatologist; OR
Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Note**
Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826

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### INFLIXIMAB

**Authority required**
Initial 1 (new patients)
Initial treatment of Crohn disease in a patient assessed by CDAI.
Initial PBS-subsidised treatment with infliximab by a gastroenterologist or a consultant physician as specified in the NOTE below, of a patient with severe refractory Crohn disease who satisfies the following criteria:
(a) has confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician as specified in the NOTE below; and
(b) has signed a patient acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and
(c) has failed to achieve an adequate response to prior systemic therapy including:
(i) a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period; and
(ii) immunosuppressive therapy including:
— azathioprine at a dose of at least 2 mg per kg daily for 3 or more months; or
— 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months; or
— methotrexate at a dose of at least 15 mg weekly for 3 or more months.

**NOTE:** Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of the accepted toxicities including severity can be found on the Medicare Australia website (www.medicareaustralia.gov.au).

The following initiation criterion indicates failure to achieve an adequate response and must be demonstrated in all patients at the time of the application:
(a) have a severity of disease activity which results in a Crohn Disease Activity Index (CDAI) Score greater than or equal to 300 as assessed.

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

The most recent CDAI assessment must be no more than 1 month old at the time of application.

Applications for authorisation must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) the completed current Crohn Disease Activity Index (CDAI) calculation sheet including the date of assessment of the patient's condition; and
(ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and
(iii) the signed patient acknowledgement.

A maximum quantity and number of repeats to provide for an initial course of infliximab consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of infliximab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
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
(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 satisfies the following criteria:

(a) has confirmed Crohn disease defined by standard clinical, endoscopic and/or imaging features, including histological evidence with the diagnosis confirmed by a gastroenterologist or consultant physician as specified in the NOTE below; and
(b) has diagnostic imaging or surgical evidence of short gut syndrome or has an ileostomy or colostomy; and
(c) has evidence of intestinal inflammation; and
(d) has signed a patient acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and
(e) has failed to achieve an adequate response to prior systemic drug therapy including:

(i) a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period; and
(ii) immunosuppressive therapy including:
   — azathioprine at a dose of at least 2 mg per kg daily for 3 or more months; or
   — 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months; or
   — methotrexate at a dose of at least 15 mg weekly for 3 or more months.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of the accepted toxicities including severity can be found on the Medicare Australia website (www.medicareaustralia.gov.au).

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the application:

(a) have evidence of intestinal inflammation, including:
   (i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; AND/OR
   (ii) faeces: higher than normal lactoferrin or calprotectin level; AND/OR
   (iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery; AND/OR
   (b) be assessed clinically as being in a high faecal output state;
   AND/OR
   (c) be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of infliximab.

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the continuing treatment restriction. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and
(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
   (i) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and
   (ii) reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; and
   (iii) date of the most recent clinical assessment; and
   (iv) the signed patient acknowledgement.

All assessments, pathology tests and diagnostic imaging studies must be made within 1 month of the date of application.
A maximum quantity and number of repeats to provide for an initial course of infliximab consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised. Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of infliximab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

The assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment

**Authority required**

Initial 2

Change or re-commencement of treatment of Crohn disease in a patient with short gut syndrome, an ostomy patient or a patient with extensive small intestine disease.

Initial PBS-subsidised treatment with infliximab by a gastroenterologist or a consultant physician as specified in the NOTE below of a patient who:

(a) has a documented history of severe refractory Crohn disease; and
(b) in this treatment cycle, has received prior PBS-subsidised treatment with infliximab or adalimumab for this condition; and
(c) has not failed PBS-subsidised therapy with infliximab for this condition more than once in the current treatment cycle.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)]. To demonstrate a response to 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).
The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the application:
(a) have severity of disease activity which results in a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220;
   AND/OR
(b) have evidence of active intestinal inflammation, including:
   (i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; AND/OR
   (ii) faeces: higher than normal lactoferrin or calprotectin level; AND/OR
   (iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery;
   AND/OR
(c) be assessed clinically as being in a high faecal output state;
   AND/OR
(d) be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of infliximab.
All tests and assessments should be performed preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment. Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the continuing treatment restriction. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and
(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and
(ii) (1) reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; or
   (2) the completed current Crohn Disease Activity Index (CDAI) calculation sheet including the dates of assessment of the patient's condition, if relevant; and
(iii) date of the most recent clinical assessment; and
(iv) the signed patient acknowledgement.

All assessments, pathology tests and diagnostic imaging studies must be made within 1 month of the date of application. A maximum quantity and number of repeats to provide for an initial course of infliximab consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised. Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of infliximab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

The assessment of the patient's response to 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, 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 PBS

Initial PBS-authorised treatment of Crohn disease in a patient assessed by CDAI who has previously received non-PBS subsidised therapy with infliximab.

Initial PBS-authorised supply for continuing treatment with infliximab as defined 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 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 subsidiised treatment under this restriction only once.

**Authority required**

Initial PBS

Initial PBS-authorised 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-authorised supply for continuing treatment with infliximab as defined 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 March 2007; and

(b) (1) has a history of extensive small intestine 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) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or
(iv) reversal of high faecal output state; or
(v) avoidance of the need for surgery or total parenteral nutrition (TPN).

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 9526
- GPO Box 9826

**HOBART TAS 7001**

**TREATMENT OF ADULT PATIENTS WITH SEVERE REFRINGATORY 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 for a maximum of 16 weeks of therapy for adalimumab and 14 weeks of therapy for infliximab.

From 1 August 2008, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

For second and subsequent courses of PBS-subsidised TNF-alfa antagonist treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Adalimumab only: Two completed authority prescriptions must be submitted with every initial application for adalimumab.

One prescription must be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats. The second prescription must be written for 2 doses of 40 mg and 2 repeats.

(b) Continuing treatment. Following the completion of an initial treatment course with a specific TNF-alfa antagonist, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing TNF-alfa antagonist treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted TNF-alfa antagonist supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised TNF-alfa antagonist is approved, a patient may swap if eligible to the alternate TNF-alfa antagonist within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Crohn Disease Activity Index (CDAI) Score, evidence of intestinal inflammation), or the prior corticosteroid therapy and immunosuppressive therapy.

A patient may trial the alternate TNF-alfa antagonist at any time, regardless of whether they are receiving therapy (initial or continuing) with a TNF-alfa antagonist at the time of the application. However, they cannot swap to a particular TNF-alfa antagonist if they have failed to respond to prior treatment with that drug two times within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to the alternate TNF-alfa antagonist should be accompanied by the approved authority prescription or remaining repeats for the TNF-alfa antagonist the patient is ceasing.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the CDAI or evidence of intestinal inflammation submitted with the first authority application for a TNF-alfa antagonist. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and Medicare Australia will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised TNF-alfa antagonist therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with a corticosteroid and at least 1 immunosuppressive agent, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the CDAI score or the indices of intestinal inflammation are measured.

(5) Patients 'grandfathered' onto PBS-subsidised treatment with adalimumab or infliximab.

A patient who commenced treatment with adalimumab for severe refractory Crohn disease prior to 9 November 2007 or infliximab prior to 7 March 2007 and who continues to receive treatment at the time of application, may qualify for treatment under the initial ‘grandfather’ treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with adalimumab or infliximab will be authorised under this criterion.
Following completion of the initial PBS-subsidised course, further applications for treatment with adalimumab or infliximab will be assessed under the continuing treatment restriction.

'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must requalify for initial treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' above for further details.

**infliximab 100 mg injection, 1 x 100 mg vial**

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<th>No. of Rpts</th>
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**Interleukin inhibitors**

- **ANAKINRA**
  
  **Authority required (STREAMLINED)**

  4920

  Moderate to severe cryopyrin associated periodic syndromes (CAPS)

  **Treatment criteria:**

  Must be treated by a rheumatologist or in consultation with a rheumatologist.

  A diagnosis of CAPS must be documented in the patient's medical records.

  **Note**

  This drug is not PBS-subsidised for conditions other than CAPS.

- **TOCILIZUMAB**
  
  **Authority required**

  Initial 1 (new and recommencing patients after a break of more than 12 months)

  Initial treatment by a rheumatologist, or under the supervision of a paediatric rheumatology treatment centre, of a patient under 18 years who:

  (a) has been diagnosed with systemic juvenile idiopathic arthritis; AND

  (b) has polyarticular course disease and either:

  (i) failure to achieve an adequate response to the following treatment regimen (see (1) below for definition of failure to achieve an adequate response):

  — oral or parenteral methotrexate at a dose of at least 15 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids for a minimum of 3 months; or

  (ii) severe intolerance of, or toxicity due to, methotrexate (see (2) below for definition of severe intolerance and toxicity); OR

  (c) has refractory systemic symptoms, demonstrated by:

  — an inability to decrease and maintain the dose of prednisolone (or equivalent) below 0.5 mg per kg per day following a minimum of 2 months of therapy; AND

  (d) has not received PBS-subsidised treatment with tocilizumab for this condition in the previous 12 months.

  (1) The following criteria indicate failure to achieve an adequate response to prior methotrexate therapy and must be demonstrated in all patients at the time of the initial application:

  (a) in a patient with polyarticular course disease:

  (i) an active joint count of at least 20 active (swollen and tender) joints; OR

  (ii) at least 4 active joints from the following list:

  — elbow, wrist, knee and/or ankle (assessed as swollen and tender); AND/OR

  — shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

  (b) in a patient with refractory systemic symptoms:

  (i) an active joint count of at least 2 active joints; AND

  (ii) persistent fever greater than 38 degrees Celsius for at least 5 out of 14 consecutive days; AND/OR

  (iii) a C-reactive protein (CRP) level and platelet count above the upper limits of normal (ULN).

  (2) Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant NSAIDs on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.

  Toxicity to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonia, or serious sepsis.

  If treatment with methotrexate alone or in combination with other treatments is contraindicated according to the relevant TGA-approved Product Information, please provide details at time of application.

  If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of this toxicity at the time of application.

  The baseline measurements of joint count, fever and/or CRP level and platelet count must be performed preferably whilst on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be provided for all subsequent continuing treatment applications. The authority application must be made in writing and must include:

(1) completed authority prescription form(s); and
(2) a completed Systemic Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) the date of assessment of severe active systemic juvenile idiopathic arthritis;
(ii) details of prior treatment including dose and duration of treatment;
(iii) pathology reports detailing CRP and platelet count where appropriate; and
(3) a signed patient or authorised guardian acknowledgement form.

The most recent systemic juvenile idiopathic arthritis assessment must be no more than 1 month old at the time of application.

A maximum of 16 weeks of treatment will be authorised under this restriction.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for two infusions (one month supply). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

Where fewer than 3 repeats are requested at the time of initial application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Assessment of a patient's response to an initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 4 weeks from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab.

If a patient fails to respond to 2 courses of treatment in a treatment cycle they will not be eligible to receive further PBS-subsidised tocilizumab therapy in that treatment cycle. A patient may re-trial tocilizumab after a minimum of 12 months have elapsed between the date the last PBS-subsidised treatment was stopped and the date of the first application under a new treatment cycle

**Authority required**

Initial 2 (retrial or recommencement of treatment after a break of less than 12 months)

Initial PBS-subsidised treatment by a rheumatologist, or under the supervision of a paediatric rheumatology treatment centre, of a patient who:
(a) has a documented history of systemic juvenile idiopathic arthritis; AND
(b) has received PBS-subsidised treatment with tocilizumab for this condition in the previous 12 months; AND
(c) has not failed PBS-subsidised therapy with tocilizumab for this condition more than once in the current treatment cycle.

The authority application must be made in writing and must include:

(1) completed authority prescription form(s); and
(2) a completed Systemic Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) pathology reports detailing CRP and platelet count where appropriate.

Applications for a patient who has received PBS-subsidised treatment with tocilizumab in this treatment cycle and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised tocilizumab treatment, within the timeframes specified below.

A maximum of 16 weeks of treatment will be authorised under this restriction.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for two infusions (one month supply). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

Where fewer than 3 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with tocilizumab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

An assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criteria. Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with tocilizumab.

Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to that course of tocilizumab.

If a patient fails to respond to 2 courses of treatment they will not be eligible to receive further PBS-subsidised tocilizumab therapy in this treatment cycle. A patient may re-trial tocilizumab after a minimum of 12 months have elapsed between the date the last PBS-subsidised treatment was stopped and the date of the first application under a new treatment cycle

**Authority required**

Initial 3 (‘grandfather’ patients)

Initial treatment by a rheumatologist, or under the supervision of a paediatric rheumatology treatment centre, of a patient who:
(a) has a documented history of systemic juvenile idiopathic arthritis; and
(b) was receiving treatment with tocilizumab prior 1 November 2011; and
(c) has demonstrated a response as specified in the criteria for continuing PBS-subsidised treatment with tocilizumab; and
(d) is receiving treatment with tocilizumab at the time of application.
To ensure consistency in determining response, the same indices of disease severity used to establish the baseline must be provided for all subsequent continuing treatment applications.

The authority application must be made in writing and must include:

(1) completed authority prescription form(s); and

(2) a completed Systemic Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) pathology reports detailing CRP and platelet count where appropriate; and

(3) a signed patient or authorised guardian acknowledgement form.

The most recent systemic juvenile idiopathic arthritis assessment must be no more than 1 month old at the time of application.

The baseline systemic juvenile idiopathic arthritis assessment must be provided and must be from immediately prior to commencing treatment with tocilizumab. (See NOTE (3) above for definition of baseline measurements to determine response.)

An assessment of the patient’s response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criteria.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with tocilizumab.

Patients are eligible to receive continuing tocilizumab treatment in courses of up to 24 weeks providing they continue to sustain the response.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for two infusions (one month supply). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 5 repeats will be authorised.

Where fewer than 5 repeats are initially requested with the authority prescription, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

A patient may only qualify for PBS-subsidised treatment under this restriction once

Authority required

Continuing treatment

Continuing treatment with tocilizumab, by a rheumatologist or under the supervision of a paediatric rheumatology treatment centre, of a patient who:

(a) has a documented history of systemic juvenile idiopathic arthritis; AND

(b) has demonstrated an adequate response to treatment with tocilizumab.

An adequate response to treatment is defined as:

(a) in a patient with polyarticular course disease:

(i) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(ii) a reduction in the number of the following major active joints, from at least 4, by at least 50%:
— elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
— shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

(b) in a patient with refractory systemic symptoms:

(i) absence of fever greater than 38 degrees Celsius in the preceding seven days; AND/OR

(ii) a reduction in the CRP level and platelet count by at least 30% from baseline; AND/OR

(iii) a reduction in the dose of corticosteroid by at least 30% from baseline.

The authority application must be made in writing and must include:

(1) completed authority prescription form(s); and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) baseline and current pathology reports detailing CRP and platelet count where appropriate.

The most recent systemic juvenile idiopathic arthritis assessment must be no more than 1 month old at the time of application.

Where the most recent course of PBS-subsidised tocilizumab treatment was approved under the Initial treatment restriction, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be provided to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised tocilizumab treatment was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Patients are eligible to receive continuing tocilizumab treatment in courses of up to 24 weeks providing they continue to sustain the response.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for two infusions (one month supply). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 5 repeats will be authorised.
Where fewer than 5 repeats are requested at the time of initial application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

If a patient fails to respond to 2 courses of treatment they will not be eligible to receive further PBS-subsidised tocilizumab therapy in this treatment cycle. A patient may re-trial tocilizumab after a minimum of 12 months have elapsed between the date the last PBS-subsidised treatment was stopped and the date of the first application under a new treatment cycle.

**Note**

Any queries concerning the arrangements to prescribe tocilizumab may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Further prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe tocilizumab should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826

HOBART TAS 7001

**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. (a) Initial treatment.
   (i) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

   (1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

   (a) Initial treatment.

   Applications for initial treatment should be made where:

   - a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
   - a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
   - a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or
   - a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

   Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

   Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab and tocilizumab, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

   A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to 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

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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.

(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.

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 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 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 initial 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 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.

Special Pricing Arrangements apply.

tocilizumab 200 mg/10 mL injection, 1 x 10 mL vial
1423X

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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 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. 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.

**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)

**Clinical criteria:**

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 tocilizumab treatment 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).

**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
HSD (Private)

Patient must have received insufficient tocilizumab therapy under the Initial 2 (change or recommencement of treatment after break of less than 12 months) restriction to complete 16 weeks treatment, AND
The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Treatment criteria:**
Must be treated by a paediatric rheumatologist; OR
Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

**Note**
Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826

HOBART TAS 7001

**Authority required**
Severe active juvenile idiopathic arthritis
Treatment Phase: Continuing treatment

**Clinical criteria:**
Patient must have a documented history of severe active juvenile idiopathic arthritis, AND
Patient must have demonstrated an adequate response to treatment with tocilizumab, AND
Patient must have received tocilizumab as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment in this treatment cycle, AND
Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

**Treatment criteria:**
Must be treated by a rheumatologist; OR
Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

For the purposes of this restriction ‘biological disease modifying anti-rheumatic drug’ and ‘bDMARD’ mean adalimumab, etanercept or tocilizumab.

An adequate response to treatment is defined as:
(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:
   (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
   (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurement of joint count submitted with the initial treatment application.

The authority application must be made in writing and must include:
(1) completed authority prescription form(s); and
(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 5 repeats will be authorised.
All applications for continuing treatment with tocilizumab must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with tocilizumab, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.
Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab.
If a patient fails to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle.

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

HOBART TAS 7001
TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient who has severe active juvenile idiopathic arthritis. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.

From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised biological therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 12 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 12 months may commence a further course of treatment within the same treatment cycle. A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 12 months (Initial 1); or

(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or

(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 12 months in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 12 months.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.

(4) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.
A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 12 months, must requalify for treatment under the Initial 1 treatment restriction.

(5) Withdrawal of treatment after sustained remission.
Withdrawal of treatment with bDMARDs should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to the Department of Human Services at the time treatment is ceased.

**Authority required**
Severe active juvenile idiopathic arthritis
Treatment Phase: Continuing Treatment – balance of supply

**Clinical criteria:**
Patient must have received insufficient tocilizumab therapy under the Continuing Treatment restriction to complete 24 weeks treatment, AND
The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Treatment criteria:**
Must be treated by a rheumatologist; OR
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**
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 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.

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after break of less than 24 months)

Clinical criteria:
Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years,
AND
Patient must have received prior PBS-subsidised treatment with adalimumab, etanercept or tocilizumab for this condition in this treatment cycle, AND
Patient must not have failed PBS-subsidised therapy with tocilizumab for this condition in the current treatment cycle, AND
Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:
Patient must be aged 18 years or older.
Treatment criteria:
Must be treated by a rheumatologist; OR
Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.

The authority application must be made in writing and must include:
(1) completed authority prescription form(s); and
(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

Applications for a patient who has received PBS-subsidised treatment with tocilizumab in this treatment cycle and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised tocilizumab treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised tocilizumab treatment was approved under either of the Initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised tocilizumab treatment was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab.

If a patient fails to respond to PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle.

An adequate response to treatment is defined as:
an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;
AND either of the following:
(a) an active joint count of fewer than 10 active (swollen and tender) joints; or
(b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or
(c) a reduction in the number of the following active joints, from at least 4, by at least 50%:
(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

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
Reply Paid 9826
GPO Box 9826

HOBART TAS 7001

Authority required
Severe active juvenile idiopathic arthritis
Treatment Phase: Continuing treatment

Clinical criteria:
Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years, AND
Patient must have demonstrated an adequate response to treatment with tocilizumab, AND
Patient must have received tocilizumab as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment in this treatment cycle, AND
Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

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

**Treatment criteria:**
- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.

An adequate response to treatment is defined as:
- An ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;
- AND either of the following:
  - (a) an active joint count of fewer than 10 active (swollen and tender) joints; or
  - (b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or
  - (c) a reduction in the number of the following active joints, from at least 4, by at least 50%:
    - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
    - (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:
- (1) completed authority prescription form(s); and
- (2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 5 repeats will be authorised.

All applications for continuing treatment with tocilizumab must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with tocilizumab, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab.

If a patient fails to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle.

**Note**

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

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

Applications for authority to prescribe should be forwarded to:
- Department of Human Services
- Prior Written Approval of Complex Drugs
- Reply Paid 9826
- GPO Box 9826

HOBART TAS 7001

**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

**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.
ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Note
Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826

HOBART TAS 7001

tocilizumab 200 mg/10 mL injection, 1 x 10 mL vial

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**TOCILIZUMAB**

**Authority required**
Severe active rheumatoid arthritis
Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months)

**Clinical criteria:**
Patient must have severe active rheumatoid arthritis, **AND**
Patient must have received no PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition in the previous 24 months, **AND**
Patient must not have failed previous PBS-subsidised treatment with tocilizumab for this condition, and have not already failed, or ceased to respond to, PBS-subsidised bDMARD treatment for this condition 5 times, **AND**
Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; **OR**
Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose,

*must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR**
Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above, must include at least 3 months continuous treatment with each of at least 2 DMARDs, with one or more of the following DMARDs being used in place of the DMARDs which are contraindicated or not tolerated: (i) azathioprine at a dose of at least 1 mg/kg per day; and/or (ii) cyclosporin at a dose of at least 2 mg/kg/day; and/or (iii) sodium aurothiomalate at a dose of 50 mg weekly, **AND**
Patient must not receive more than 16 weeks of treatment under this restriction.

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

**Treatment criteria:**
Must be treated by a rheumatologist; **OR**
Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.
For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab or tocilizumab.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate.
The maximum tolerated dose of methotrexate must be documented in the application, if applicable.
The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.
The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs. If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application.

The authority application must be made in writing and must include:
(1) a completed authority prescription form(s); and
(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form; and
(3) a signed patient acknowledgement.

At the time of the authority application, medical practitioners should request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 8 mg per kg. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

If a patient fails to demonstrate a response to treatment with tocilizumab under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:
- an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either
  (a) a total active joint count of at least 20 active (swollen and tender) joints; or
  (b) at least 4 active joints from the following list of major joints:
    (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
    (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).
- The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.
- If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Where the baseline joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP is provided with the initial application, the same marker will be used to determine response.

Note
The Department of Human Services website (www.humanservices.gov.au) has details of the toxicities, including severity, which will be accepted for the following purposes:
- (a) exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose;
- (b) substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial;
- (c) exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy.

Authority required
Severe active rheumatoid arthritis
Treatment Phase: Initial treatment - Initial 2 (change or re-commencement of treatment after break of less than 24 months).

Clinical criteria:
Patient must have a documented history of severe active rheumatoid arthritis, AND
Patient must have received prior PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition and are eligible to receive further bDMARD therapy, AND
Patient must not receive more than 16 weeks of treatment under this restriction.

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

Treatment criteria:
Must be treated by a rheumatologist; OR
Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.
For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab or tocilizumab.

The authority application must be made in writing and must include:
(1) completed authority prescription form(s); and
(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.
At the time of authority application, medical practitioners should request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 8 mg per kg. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

Applications for a patient who has received PBS-subsidised treatment with tocilizumab and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient’s most recent course of PBS-subsidised tocilizumab treatment, within the timeframes specified below.
Where the most recent course of PBS-subsidised tocilizumab treatment was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised tocilizumab treatment was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab.

If a patient fails to demonstrate a response to a treatment with tocilizumab under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:
   (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
   (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Note

Special Pricing Arrangements apply.

Authority required
Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months) or Initial 2 (change or recommencement of treatment after break of less than 24 months) – balance of supply.

Clinical criteria:
Patient must have received insufficient tocilizumab therapy under the Initial 1 (new patient or patient recommencing treatment after break of more than 24 months) restriction to complete 16 weeks treatment; OR
Patient must have received insufficient tocilizumab therapy under the Initial 2 (change or recommencement of treatment after break of less than 24 months) restriction to complete 16 weeks treatment, AND
The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Treatment criteria:
Must be treated by a rheumatologist; OR
Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Note

Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826

HOBART TAS 7001

Authority required
Severe active rheumatoid arthritis

Treatment Phase: Continuing treatment.

Clinical criteria:
Patient must have a documented history of severe active rheumatoid arthritis, AND
Patient must have demonstrated an adequate response to treatment with tocilizumab, AND
Patient must have received tocilizumab as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment, AND
Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

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

Treatment criteria:
Must be treated by a rheumatologist; OR
Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab or tocilizumab.

An adequate response to treatment is defined as:
an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;
AND either of the following:
(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:
(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:
(1) completed authority prescription form(s); and
(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners should request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 8 mg per kg. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 5 repeats will be authorised.

All applications for continuing treatment with tocilizumab must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with tocilizumab, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab.

If a patient fails to demonstrate a response to treatment with tocilizumab under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

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

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

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826

HOBBART TAS 7001

TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab) and the T-cell co-stimulation modulator (abatacept).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:
- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy;
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab and tocilizumab, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:
Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient’s weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:
A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients:
A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to regally 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 swap an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept patients:
Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.
the Department of Human Services will determine whether a response to treatment has been demonstrated based on the
baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements. To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

**Authority required**

Severe active rheumatoid arthritis

**Treatment Phase:** Continuing Treatment – balance of supply.

**Clinical criteria:**

Patient must have received insufficient 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 9825
GPO Box 9826
HOBART TAS 7001

tocilizumab 200 mg/10 mL injection, 1 x 10 mL vial
9672C

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**Calcineurin inhibitors**

- **CYCLOSPORIN**

  **Caution**
  Careful monitoring of patients is mandatory.

  **Authority required**
  For use by organ or tissue transplant recipients

  cyclosporin 50 mg/mL injection, 10 x 1 mL ampoules
  6109M

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- **CYCLOSPORIN**

  **Caution**
  Careful monitoring of patients is mandatory.

  **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
ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

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

cyclosporin 10 mg capsule, 60

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cyclosporin 100 mg capsule, 30

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- TACROLIMUS

Caution
Careful monitoring of patients is mandatory.

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

tacrolimus 1 mg capsule, 100

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tacrolimus 1 mg capsule: modified release, 60 capsules

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tacrolimus 500 microgram capsule, 100

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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

**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

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).

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

Authority required
Multiple myeloma
Treatment Phase: Continuing PBS-subsidised treatment

Clinical criteria:
Patient must have previously received an authority prescription for lenalidomide, AND
Patient must not have progressive disease, AND
The treatment must be as monotherapy; OR
The treatment must be in combination with dexamethasone.

Progressive disease is defined as at least 1 of the following:
(a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or
(b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or
(c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase of the difference between involved free light chain and uninvolved free light chain; or
(d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or
(e) an increase in the size or number of lytic bone lesions (not including compression fractures); or
(f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or
(g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Patients receiving lenalidomide under the PBS listing must be registered in the i-access risk management program.

Note
Authority applications for continuing treatment may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authority to prescribe should be forwarded to:
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### RITUXIMAB

**Authority required**

Severe active rheumatoid arthritis

**Treatment Phase:** Initial treatment - Initial 1 (patient recommencing treatment after a break of more than 24 months)

**Clinical criteria:**

- Patient must have severe active rheumatoid arthritis, **AND**
- Patient must have failed to respond to at least 1 PBS-subsidised tumour necrosis factor (TNF) alfa antagonist, **AND**
- Patient must have received no PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition in the previous 24 months, **AND**
- Patient must not have failed previous PBS-subsidised treatment with rituximab for this condition, and have not already failed, or ceased to respond to, PBS-subsidised bDMARD treatment for this condition 5 times, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; **OR**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; **OR**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above, must include at least 3 months continuous treatment with each of at least 2 DMARDs, with one or more of the following DMARDs being used in place of the DMARDs which are contraindicated or not tolerated: (i) azathioprine at a dose of at least 1 mg/kg per day; and/or (ii) cyclosporin at a dose of at least 2 mg/kg/day; and/or (iii) sodium aurothiomalate at a dose of 50 mg weekly, **AND**
- Patient must not receive more than 2 infusions of rituximab under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

For the purposes of this restriction ‘TNF alfa antagonist means adalimumab, certolizumab pegol, etanercept, golimumab and infliximab.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab or tocilizumab.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.
ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application.

The authority application must be made in writing and must include:

(1) completed authority prescription form(s); and
(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form; and
(3) a signed patient acknowledgement.

Assessment of a patient's response to an initial course of treatment must be made at least 12 weeks after the first infusion so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services within 4 weeks of the date it was conducted. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with rituximab.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction.

If a patient who fails to demonstrate a response to treatment with rituximab under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

A patient who fails to demonstrate a response to rituximab treatment and who qualifies to trial an alternate bDMARD according to the interchangeability arrangements for bDMARDs for the treatment of severe rheumatoid arthritis, may do so without having to have a 22 week treatment-free period.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

- an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either
  - (a) a total active joint count of at least 20 active (swollen and tender) joints; or
  - (b) at least 4 active joints from the following list of major joints:
    (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
    (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).
- The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Where the baseline joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP is provided with the initial application, the same marker will be used to determine response.

Note

The Department of Human Services website (www.humanservices.gov.au) has details of the toxicities, including severity, which will be accepted for the following purposes:

- exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose;
- 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.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or re-commencement of treatment after break of less than 24 months).

Clinical criteria:

- Patient must have a documented history of severe active rheumatoid arthritis, AND
- Patient must have failed to respond to at least 1 PBS-subsidised tumour necrosis factor (TNF) alfa antagonist, AND
- Patient must have received prior PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition and are eligible to receive further bDMARD therapy, AND
- Patient must not receive more than 2 infusions of rituximab under this restriction, AND

The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

For the purposes of this restriction ‘TNF’ alfa antagonist means adalimumab, certolizumab pegol, etanercept, golimumab and infliximab.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab or tocilizumab.
The authority application must be made in writing and must include:

(a) completed authority prescription form(s); and
(b) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

Applications for a patient who has received PBS-subsidised treatment with rituximab and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised rituximab treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised rituximab treatment was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response at least 12 weeks after the first infusion. This assessment must be submitted no later than 4 weeks from the date of the assessment.

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent provided they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The demonstration of response must be submitted within 4 weeks of assessment.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with rituximab.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction.

If a patient fails to demonstrate a response to treatment with rituximab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

If a patient fails to demonstrate a response to a treatment with rituximab and who qualify to trial an alternate bDMARD according to the interchangeability arrangements for bDMARDs for the treatment of severe rheumatoid arthritis, may do so without having to have a 22 week treatment-free period.

An adequate response to treatment is defined as:

- an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;
- AND either of the following:
  (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
  (b) a reduction in the number of the following active joints, from at least 4, by at least 50%:
     (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
     (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Continuing treatment

**Clinical criteria:**

Patient must have a documented history of severe active rheumatoid arthritis, AND

Patient must have demonstrated an adequate response to treatment with this drug, AND

Patient must have received this drug as the most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition, AND

Patient must not receive more than 2 infusions of rituximab under this restriction, AND

The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

**Population criteria:**

Patient must have a documented history of severe active rheumatoid arthritis, AND

Patient must have demonstrated an adequate response to treatment with this drug, AND

Patient must have received this drug as the most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition, AND

Patient must not receive more than 2 infusions of rituximab under this restriction, AND

The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

**Treatment criteria:**

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab or tocilizumab.

The authority application must be made in writing and must include:

(a) completed authority prescription form(s); and
(b) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent provided they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The demonstration of response must be submitted within 4 weeks of assessment.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with rituximab.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction.

If a patient fails to demonstrate a response to treatment with rituximab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

An adequate response to treatment is defined as:

- an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;
- AND either of the following:
  (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
  (b) a reduction in the number of the following active joints, from at least 4, by at least 50%:
     (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
Note
Special Pricing Arrangements apply.

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826

HOBART TAS 7001

TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alpha antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab) and the T-cell co-stimulation modulator (abatacept).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alpha antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:

- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy;
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alpha antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD was stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010:

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or

(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or

(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or

(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab and tocilizumab, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current course of treatment.

Abatacept patients:

Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient’s weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.
Rituximab patients:
A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients:
A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept patients:
Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

**rituximab 500 mg/50 mL injection, 1 x 50 mL vial**

<table>
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<tr>
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</tr>
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<tbody>
<tr>
<td>9611W</td>
<td>2079.67</td>
<td>Mabthera [RO]</td>
</tr>
</tbody>
</table>

### THALIDOMIDE

**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.

**Authority required**
Multiple myeloma

**Note**
Patients receiving thalidomide under the PBS listing must be registered in the i-access risk management program.

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<tr>
<th>thalidomide 100 mg capsule, 28</th>
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### MUSCULO-SKELETAL SYSTEM

### MUSCLE RELAXANTS

**MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS**

**Other centrally acting agents**

#### BACLOFEN

**Authority required**
Severe chronic spasticity, where oral antispastic agents have failed or have caused unacceptable side effects, in patients with chronic spasticity of cerebral origin

**Authority required**
Severe chronic spasticity, where oral antispastic agents have failed or have caused unacceptable side effects, in patients with chronic spasticity due to multiple sclerosis

**Authority required**
Severe chronic spasticity, where oral antispastic agents have failed or have caused unacceptable side effects, in patients with chronic spasticity due to spinal cord injury

**Authority required**
Severe chronic spasticity, where oral antispastic agents have failed or have caused unacceptable side effects, in patients with chronic spasticity due to spinal cord disease

**baclofen 10 mg/5 mL injection: intrathecal, 1 x 5 mL ampoule**

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### DRUGS FOR TREATMENT OF BONE DISEASES

#### DRUGS AFFECTING BONE STRUCTURE AND MINERALIZATION

**Bisphosphonates**

#### IBANDRONIC ACID

**Authority required**
Bone metastases from breast cancer

**ibandronic acid 6 mg/6 mL injection, 1 x 6 mL vial**

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#### PAMIDRONATE DISODIUM

**Authority required**
Hypercaemia of malignancy

**Clinical criteria:**
Patient must have a malignancy refractory to anti-neoplastic therapy.

**pamidronate disodium 15 mg/5 mL injection, 1 x 5 mL vial**

<table>
<thead>
<tr>
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**pamidronate disodium 60 mg/10 mL injection, 1 x 10 mL vial**

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### PAMIDRONATE DISODIUM

**Authority required**
Hypercaemia 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.

pamidronate disodium 30 mg injection [2 x 30 mg vials] (&) inert substance diluent [2 x 10 mL ampoules], 1 pack

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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.

pamidronate disodium 90 mg injection [1 x 90 mg vial] (&) inert substance diluent [1 x 10 mL ampoule], 1 pack

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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.

pamidronate disodium 30 mg/10 mL injection, 1 x 10 mL vial

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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.

pamidronate disodium 90 mg/10 mL injection, 1 x 10 mL vial

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Note
Pharmaceutical benefits that have the form disodium pamidronate powder for I.V. infusion 90 mg (after reconstitution) and pharmaceutical benefits that have the form disodium pamidronate concentrated injection 90 mg are equivalent for the purposes of substitution.

zoledronic acid 4 mg/5 mL injection, 1 x 5 mL vial

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Note
Special Pricing Arrangements apply.

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.

**levodopa 20 mg/mL + carbidopa monohydrate 5 mg/mL gel: intestinal, 7 x 100 mL bags**

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**Dopamine agonists**

- **APOMORPHINE**

  **Authority required**
  Parkinson disease

  **Clinical criteria:**
  Patient must have experienced severely disabling motor fluctuations which have not responded to other therapy.

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

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- **apomorphine hydrochloride 20 mg/2 mL injection, 5 x 2 mL ampoules**

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- **apomorphine hydrochloride 50 mg/10 mL injection: subcutaneous infusion, 5 x 10 mL syringes**

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- **apomorphine hydrochloride 50 mg/5 mL injection, 5 x 5 mL ampoules**

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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 (eGPMS) or Clopineconnect.

clozapine 100 mg tablet, 100

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<td></td>
<td></td>
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clozapine 200 mg tablet, 100

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clozapine 25 mg tablet, 100

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</table>
**OMALIZUMAB**

**Authority required**

Uncontrolled severe allergic asthma

Treatment Phase: Initial treatment

**Clinical criteria:**

Patient must be under the care of the same physician for at least 12 months, AND

Patient must have 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 the following standard clinical features: (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

Patient must have a duration of asthma of at least 1 year, AND

Patient must have forced expiratory volume (FEV1) less than or equal to 80% predicted, documented on 3 or more occasions in the previous 12 months, AND

Patient must have past or current evidence of atopy, documented by skin prick testing or RAST, AND

Patient must have total serum human immunoglobulin E greater than or equal to 76 IU/mL, AND

Patient must have 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

Patient must have failed to achieve adequate control with optimised asthma therapy, despite formal assessment of and adherence to correct inhaler technique, which has been documented, AND

Patient must not receive more than 28 weeks of treatment under this restriction.

**Population criteria:**

Patient must be aged 12 years or older.

**Treatment criteria:**

Must be treated by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma.

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 formoterol 12 micrograms bd) for at least 12 months, unless contraindicated or not tolerated, AND

(ii) treatment with oral corticosteroids, either daily oral corticosteroids for at least 6 weeks, OR a cumulative dose of oral corticosteroids of at least 500 mg prednisolone equivalent in the previous 12 months, 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.

The initial IgE assessment must be no more than 12 months old at the time of 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 receiving optimised asthma therapy 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 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 22 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 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 within this timeframe, the patient will be deemed to have failed to respond to treatment with omalizumab.

### RESPIRATORY SYSTEM

#### DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES

**OTHER SYSTEMIC DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES**

**Other systemic drugs for obstructive airway diseases**

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<thead>
<tr>
<th>Drug Name and Manufacturer</th>
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</table>
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.

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.

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, 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 in the past 12 months while receiving optimised asthma therapy (date and treatment); and
(iii) the signed patient acknowledgement; and
(c) the IgE pathology report; and
(d) a completed Asthma Control Questionnaire (ACQ-5) calculation sheet including the date of assessment of the patient's symptoms.

Note
The Department of Human Services website (www.humanservices.gov.au) has 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.

It is recommended that an application for continuing treatment is submitted at the time of the 22 to 26 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised omalizumab treatment.

Authority required
Uncontrolled severe allergic asthma
Treatment Phase: Initial treatment - balance of supply
Clinical criteria:
Patient must have received insufficient therapy with this drug under the Initial treatment restriction to complete 28 weeks treatment, AND
The treatment must provide no more than the balance of up to 28 weeks treatment available under the above restriction.

Treatment criteria:
Must be treated by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma.

Note
Authority approval for sufficient therapy to complete a maximum of 28 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 28 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
Uncontrolled severe allergic asthma
Treatment Phase: Continuing treatment
Clinical criteria:
Patient must have a documented history of severe allergic asthma, AND
Patient must have demonstrated or sustained an adequate response to treatment with this drug, AND
Patient must not receive more than 24 weeks of treatment under this restriction.

Treatment criteria:
Must be treated by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma.

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.

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 18 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. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted 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 within this timeframe, the patient will be deemed to have failed to respond to treatment with omalizumab.

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.

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.

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 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.

**Note**

If the same physician cannot assess the patient please call the Department of Human Services on 1800 700 270.

For copies of the ACQ please contact Novartis Medical Information on 1800 671 203 or medinfo.phauno@novartis.com

It is recommended that an application for continuing treatment is submitted at the time of the 18 to 22 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised omalizumab treatment.

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

Prescribing information (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 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.

(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.

(2) 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 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 the Department of Human Services 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) 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.

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.humanservices.gov.au or...
RESPIRATORY SYSTEM

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).

**Authority required**
Uncontrolled severe allergic asthma

**Treatment Phase:** Continuing treatment - balance of supply

**Clinical criteria:**
Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, AND
The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Treatment criteria:**
Must be treated by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma.

**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
Special Pricing Arrangements apply.

**omalizumab 150 mg/mL injection, 1 x 1 mL syringe**

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**omalizumab 75 mg/0.5 mL injection, 1 x 0.5 mL syringe**

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**COUGH AND COLD PREPARATIONS**

**EXPECTORANTS, EXCL. COMBINATIONS WITH COUGH SUPPRESSANTS**

**Mucolytics**

**DORNASE ALFA**

**Authority required**
Cystic fibrosis

**Clinical criteria:**
Patient must have a forced vital capacity (FVC) greater than 40% predicted for age, gender and weight, AND
Patient must have evidence of chronic suppurative lung disease (cough and sputum most days of the week, or greater than 3 respiratory tract infections of more than 2 weeks' duration in any 12 months, or objective evidence of obstructive airways disease).

**Population criteria:**
Patient must be 5 years of age or older.
Patient must be assessed at a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis. The prescribing of dornase alfa therapy under the HSD program is limited to such physicians. If attendance at such a unit is not possible because of geographical isolation, management (including prescribing) may be by a specialist physician or paediatrician in consultation with such a unit.
The measurement of lung function is to be conducted by independent (other than the treating doctor) experienced personnel at an established lung function testing laboratory, unless this is not possible because of geographical isolation.
Prior to dornase alfa therapy, a baseline measurement of forced expiratory volume in 1 second (FEV1) must be undertaken during a stable period of the disease.

Initial therapy is limited to 3 months treatment with dornase alfa at a dose of 2.5 mg daily.

FEV1 measurement (single test under conditions as above) and a global assessment of the patient involving the patient, the patient's family (in the case of paediatric patients), the treating physician(s) and an additional independent member of the cystic fibrosis treatment team must be undertaken and documented following 3 months of initial therapy.

To be eligible for continued PBS-subsidised treatment with dornase alfa following 3 months of initial treatment:
(1) the patient must demonstrate no deterioration in FEV1 compared to baseline; AND
(2) the patient or the patient's family (in the case of paediatric patients) must report improvement in the patient's airway clearance; AND
(3) the treating physician(s) must report a benefit in the clinical status of the patient.
Further reassessments involving the patient, the patient’s family (in the case of paediatric patients), the treating physician(s) and an additional independent member of the cystic fibrosis treatment team must be undertaken and documented at six-monthly intervals to establish that 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

**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.

It is highly desirable that all patients be included in the national cystic fibrosis patient database.

dornase alfa 2.5 mg/2.5 mL inhalation: solution, 30 x 2.5 mL ampoules

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**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**

**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.

It is highly desirable that all patients be included in the national cystic fibrosis patient database.

**MANNITOL**

Pack containing 280 capsules containing powder for inhalation 40 mg and 2 inhalers, 1

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**OTHER RESPIRATORY SYSTEM PRODUCTS**

**IVACAFTOR**

**Authority required**

Cystic fibrosis

Treatment Phase: Initial treatment – New patients

**Clinical criteria:**
Patient must be assessed through a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis. If attendance at such a unit is not possible because of geographical isolation, management (including prescribing) may be in consultation with such a unit, **AND**

Patient must have G551D mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene on at least one allele; **OR**

Patient must have other gating (class III) mutation in the CFTR gene on at least one allele, **AND**

The treatment must be given concomitantly with standard therapy for this condition.

**Population criteria:**

Patient must be 6 years of age or older.

Patients receiving PBS-subsidised ivacaftor must be registered in the Australian Cystic Fibrosis Database Registry.

Treatment must not be given to a patient who has an acute upper or lower respiratory infection, pulmonary exacerbation, or changes in therapy (including antibiotics) for pulmonary disease in the last 4 weeks prior to commencing this drug.

Dosage of ivacaftor must not exceed the dose of 150 mg twice a week, if the patient is concomitantly receiving one of the following strong CYP3A4 drugs inhibitors: boceprevir, clarithromycin, conivaptan, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, mibefradil, nefazodone, neflnavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole.

Where a patient is concomitantly receiving a strong CYP3A4 inhibitor, a single supply of 56 tablets of ivacaftor will last for 28 weeks.

Dosage of ivacaftor must not exceed the dose of 150 mg daily, if the patient is concomitantly receiving one of the following moderate CYP3A4 inhibitors: amprenavir, aprepitant, atazanavir, darunavir/ritonavir, diltiazem, erythromycin, fluconazole, fosamprenavir, imatinib, verapamil.

Where a patient is concomitantly receiving a moderate CYP3A4 inhibitor, a single supply of 56 tablets of ivacaftor will last for 8 weeks.

Ivacaftor is not PBS-subsidised for this condition as a sole therapy.

Ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers:

- Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John's wort
- Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, nafcillin

Weak CYP3A4 inducers: armodafinil, echnacine, pioglitazone, prednisone, rufinamide.

The authority application must be in writing and must include:

1. a completed authority prescription form; and
2. a completed Cystic Fibrosis Ivacaftor Authority Application Supporting Information Form; and
3. a signed patient acknowledgement; or an acknowledgement signed by a parent or authorised guardian, if applicable; and
4. a copy of the pathology report detailing the molecular testing for G551D mutation or other gating (class III) mutation on the CFTR gene; and
5. the result of a FEV1 measurement performed within a month prior to the date of application. Note: FEV1, must be measured in an accredited pulmonary function laboratory, with documented no acute infective exacerbation at the time FEV1 is measured; and
6. evidence that the patient has either chronic sinopulmonary disease or gastrointestinal and nutritional abnormalities; and
7. a copy of a current medication history, including any CYP3A4 inhibitors and/or CYP3A4 inducers; and
8. a copy of a sweat chloride result; and
9. height and weight measurements at the time of application; and
10. a baseline measurement of the number of days of CF-related hospitalisation (including hospital-in-the-home) in the previous 12 months.

**Authority required**

Cystic fibrosis

Treatment Phase: Continuing treatment

**Clinical criteria:**

Patient must be assessed through a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis. If attendance at such a unit is not possible because of geographical isolation, management (including prescribing) may be in consultation with such a unit, **AND**

Patient must have received PBS-subsidised initial therapy with ivacaftor, given concomitantly with standard therapy, for this condition, **AND**

Patient must not receive more than 24 weeks of treatment under this restriction, **AND**

The treatment must be given concomitantly with standard therapy for this condition.

**Population criteria:**

Patient must be 6 years of age or older.

Patients receiving PBS-subsidised ivacaftor must be registered in the Australian Cystic Fibrosis Database Registry.

Treatment must not be given to a patient who has an acute upper or lower respiratory infection, pulmonary exacerbation, or changes in therapy (including antibiotics) for pulmonary disease in the last 4 weeks prior to commencing this drug.

Patients who have an acute infective exacerbation at the time of assessment for continuing therapy may receive an additional one month's supply in order to enable the assessment to be repeated following resolution of the exacerbation.

Dosage of ivacaftor must not exceed the dose of 150 mg twice a week, if the patient is concomitantly receiving one of the following strong CYP3A4 drugs inhibitors: boceprevir, clarithromycin, conivaptan, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, mibefradil, nefazodone, neflnavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole.
Where a patient is concomitantly receiving a strong CYP3A4 inhibitor, a single supply of 56 tablets of ivacaftor will last for 28 weeks.

Dosage of ivacaftor must not exceed the dose of 150 mg daily, if the patient is concomitantly receiving one of the following moderate CYP3A4 inhibitors: amprenavir, aprepitant, atazanavir, darunavir/ritonavir, diltiazem, erythromycin, fluconazole, fosamprenavir, imatinib, verapamil.

Where a patient is concomitantly receiving a moderate CYP3A4 inhibitor, a single supply of 56 tablets of ivacaftor will last for 8 weeks.

Ivacaftor is not PBS-subsidised for this condition as a sole therapy.

Ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers:

- Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John’s wort
- Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, nafcillin
- Weak CYP3A4 inducers: armodafinil, echinacea, pioglitazone, prednisone, rufinamide.

The authority application must be in writing and must include:

1. A completed authority prescription form; and
2. A completed Cystic Fibrosis Ivacaftor Authority Continuing Application Supporting Information Form; and
3. The result of a FEV1 measurement performed within one month prior to the date of application. Note: FEV1 must be measured in an accredited pulmonary function laboratory, with documented no acute infective exacerbation at the time FEV1 is measured; and
4. A copy of a current medication history, including any CYP3A4 inhibitors and/or CYP3A4 inducers; and
5. A recent sweat chloride result; and
6. Height and weight measurements at the time of application; and
7. A measurement of number of days of CF-related hospitalisation (including hospital in the home) in the previous 6 months.

**Authority required**

Cystic fibrosis

**Treatment Phase: Initial treatment - Grandfather patients**

**Clinical criteria:**

- Patient must be assessed through a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis. If attendance at such a unit is not possible because of geographical isolation, management (including prescribing) may be in consultation with such a unit, AND
- Patient must have G551D mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene on at least 1 allele; OR
- Patient must have other gating (class III) mutation in the CFTR gene on at least 1 allele, AND
- Patient must have received treatment with ivacaftor for this condition prior to 1 December 2014, AND
- Patient must have received treatment with ivacaftor within the last 6 months at the time of application, AND
- Patient must not receive more than 24 weeks of treatment under this restriction, AND
- The treatment must be given concomitantly with standard therapy for this condition.

**Population criteria:**

- Patient must be 6 years of age or older.
- Patients receiving PBS-subsidised ivacaftor must be registered in the Australian Cystic Fibrosis Database Registry.
- Treatment must not be given to a patient who has an acute upper or lower respiratory infection, pulmonary exacerbation, or changes in therapy (including antibiotics) for pulmonary disease in the last 4 weeks prior to commencing this drug.

Dosage of ivacaftor must not exceed the dose of 150 mg twice a week, if the patient is concomitantly receiving one of the following strong CYP3A4 drugs inhibitors: boceprevir, clarithromycin, conivaptan, indinavir, itraconazole, ketocanazole, lopinavir/ritonavir, mibefradil, nefazodone, neflinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole.

Where a patient is concomitantly receiving a strong CYP3A4 inhibitor, a single supply of 56 tablets of ivacaftor will last for 28 weeks.

Dosage of ivacaftor must not exceed the dose of 150 mg daily, if the patient is concomitantly receiving one of the following moderate CYP3A4 inhibitors: amprenavir, aprepitant, atazanavir, darunavir/ritonavir, diltiazem, erythromycin, fluconazole, fosamprenavir, imatinib, verapamil.

Where a patient is concomitantly receiving a moderate CYP3A4 inhibitor, a single supply of 56 tablets of ivacaftor will last for 8 weeks.

Ivacaftor is not PBS-subsidised for this condition as a sole therapy.

Ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers:

- Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John’s wort
- Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, nafcillin
- Weak CYP3A4 inducers: armodafinil, echinacea, pioglitazone, prednisone, rufinamide.

The authority application must be in writing and must include:

1. A completed authority prescription form; and
2. A completed Cystic Fibrosis Ivacaftor Authority Continuing Application Supporting Information Form; and
3. A signed patient acknowledgement; or an acknowledgement signed by a parent or authorised guardian, if applicable; and
4. A copy of the pathology report detailing the molecular testing for G551D mutation or other gating (class III) mutation on the CFTR gene performed prior to commencing treatment with ivacaftor; and
5. The result of a FEV1 measurement performed prior to commencing treatment with ivacaftor for this condition; and
VARIOUS

Schedule of Pharmaceutical Benefits

(6) the result of a FEV1 measurement performed within a month prior to date of application. Note: FEV1, must be measured in an accredited pulmonary function laboratory, with documented no acute infective exacerbation at the time FEV1 is measured; and

(7) evidence that the patient had either chronic sinopulmonary disease or gastrointestinal and nutritional abnormalities prior to commencing treatment with ivacaftor for this condition; and

(8) a copy of a current medication history, including any CYP3A4 inhibitors and/or CYP3A4 inducers; and

(9) a copy of sweat chloride result performed prior to commencing treatment with ivacaftor for this condition; and

(10) a recent height and weight measurements performed immediately prior to commencement of ivacaftor; and

(11) evidence that the patient had either chronic sinopulmonary disease or gastrointestinal and nutritional abnormalities prior to commencing treatment with ivacaftor for this condition; and

(12) a copy of a current medication history, including any CYP3A4 inhibitors and/or CYP3A4 inducers; and

(13) a baseline measurement of number of days of CF-related hospitalisation (including hospital-in-the home) in the 12 months prior to commencement of ivacaftor; and

(14) a measurement of the number of days of CF-related hospitalisation (including hospital-in-the home) in the 6 months prior to the date of application; and

(15) dates of prior ivacaftor therapy.

Note

Special Pricing Arrangements apply.

No increase in the maximum number of repeats may 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

**ivacaftor 150 mg tablet, 56**

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**VARIOUS**

**ALL OTHER THERAPEUTIC PRODUCTS**

Iron chelating agents

**DEREFASIROX**

**Authority required**

Chronic iron overload in patients with disorders of erythropoiesis

**Note**

Special Pricing Arrangements apply.

**deferasirox 125 mg tablet: dispersible, 28**

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**deferasirox 250 mg tablet: dispersible, 28**

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**deferasirox 500 mg tablet: dispersible, 28**

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**DEREFERIPRONE**

**Authority required**

Iron overload in patients with thalassaemia major who are unable to take desferrioxamine therapy

**Authority required**

Iron overload in patients with thalassaemia major in whom desferrioxamine therapy has proven ineffective
deferiprone 100 mg/mL oral liquid, 250 mL

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deferiprone 500 mg tablet, 100

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### DESFERRIOXAMINE

**Authority required**

Disorders of erythropoiesis associated with treatment-related chronic iron overload

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desferrioxamine mesylate 500 mg injection, 10 x 500 mg vials

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### LANTHANUM

**Authority required**

Hyperphosphataemia

**Treatment Phase: Initiation and stabilisation**

**Clinical criteria:**

- The condition must not be adequately controlled by calcium, AND
- Patient must have a serum phosphate of greater than 1.6 mmol per L at the commencement of therapy; OR
- The condition must be where a serum calcium times phosphate product is greater than 4 at the commencement of therapy, AND
- The treatment must not be used in combination with any other phosphate binding agents.

**Treatment criteria:**

Patient must be undergoing dialysis for chronic kidney disease.

#### LANTHANUM Tablet, chewable, 1000 mg (as carbonate hydrate), 90

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#### LANTHANUM Tablet, chewable, 500 mg (as carbonate hydrate), 90

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#### LANTHANUM Tablet, chewable, 750 mg (as carbonate hydrate), 90

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### SEVELAMER

**Authority required**

Hyperphosphataemia

**Treatment Phase: Initiation and stabilisation**

**Clinical criteria:**

- The condition must not be adequately controlled by calcium, AND
- Patient must have a serum phosphate of greater than 1.6 mmol per L at the commencement of therapy; OR
- The condition must be where a serum calcium times phosphate product is greater than 4 at the commencement of therapy, AND
- The treatment must not be used in combination with any other phosphate binding agents.

**Treatment criteria:**

Patient must be undergoing dialysis for chronic kidney disease.

#### sevelamer hydrochloride 800 mg tablet, 180

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**SUCROFERRIC OXYHYDROXIDE**

*Authority required*

Hyperphosphataemia

**Treatment Phase: Initiation and stabilisation**

**Clinical criteria:**

The condition must not be adequately controlled by calcium, **AND**

Patient must have a serum phosphate of greater than 1.6 mmol per L at the commencement of therapy; **OR**

The condition must be where a serum calcium times phosphate product is greater than 4 at the commencement of therapy, **AND**

The treatment must not be used in combination with any other phosphate binding agents.

**Treatment criteria:**

Patient must be undergoing dialysis for chronic kidney disease.

---

**iron (as sucroferric oxyhydroxide) 500 mg tablet: chewable, 90**

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Highly Specialised Drugs Program (Public Hospital)

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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:

1. a platelet count of less than or equal to 20,000 million per L;

OR

2. a platelet count of 20-30,000 million per L, where the patient is experiencing significant bleeding or has a history of significant bleeding in this platelet range.

The authority application must be made in writing and must include:

1. a completed authority prescription form,
2. a signed patient acknowledgement,
3. a completed Idiopathic Thrombocytopenic Purpura Initial PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)],
4. a copy of a full blood count pathology report supporting the diagnosis of ITP, and
5. where the application is sought on the basis of a medical contraindication to surgery, a signed and dated letter from the clinician making this assessment which includes the date upon which the patient was assessed for surgery and the clinical grounds upon which surgery is contraindicated.

A maximum of 24 weeks of treatment with eltrombopag will be authorised under this criterion

Authority required

Initial (grandfather patients)

Initial treatment, as the sole PBS-subsidised thrombopoietin receptor agonist (TRA), of severe thrombocytopenia in an adult patient with severe chronic immune (idiopathic) thrombocytopenic purpura (ITP) who was receiving treatment with eltrombopag prior to 1 November 2011 and in whom the criteria for initial treatment can be demonstrated to have been met at the time eltrombopag was commenced.

The authority application must be made in writing and must include:

1. a completed authority prescription form,
2. a signed patient acknowledgement,
3. a completed Idiopathic Thrombocytopenic Purpura Initial PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)], and
4. where the application is sought on the basis of a medical contraindication to surgery, a signed and dated letter from the clinician making this assessment which includes the date upon which the patient was assessed for surgery and the clinical grounds upon which surgery is contraindicated.

A maximum of 24 weeks of treatment with eltrombopag will be authorised under this criterion

Authority required

Continuing therapy or re-initiation after a break in therapy

First period of PBS-subsidised continuing treatment or re-initiation of interrupted PBS-subsidised treatment, as the sole PBS-subsidised thrombopoietin receptor agonist (TRA), of severe thrombocytopenia in an adult patient with chronic immune (idiopathic) thrombocytopenic purpura (ITP) who has displayed a sustained platelet response to treatment with eltrombopag during the initial period of PBS-subsidised treatment.

For the purposes of this restriction, a sustained platelet response is defined as:

(a) use of rescue medication (corticosteroids or immunoglobulins) on no more than one occasion during the initial period of PBS-subsidised eltrombopag,

AND either of the following:

(b) a platelet count greater than or equal to 50,000 million per L on at least four (4) occasions, each at least one week apart;

OR

(c) a platelet count greater than 30,000 million per L and which is double the baseline (pre-treatment) platelet count on at least four (4) occasions, each at least one week apart.
Applications for the first period of continuing PBS-subsidised treatment or re-initiation of interrupted treatment must be made in writing and must include:
(1) a completed authority prescription form, and
(2) a completed Idiopathic Thrombocytopenic Purpura Continuing PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)], and
(3) copies of the platelet count pathology reports (unless previously provided for patients re-initiating therapy).
The most recent platelet count must be no more than one month old at the time of application.
A maximum of 24 weeks of treatment with eltrombopag will be authorised under this criterion.
Where fewer than 5 repeats are initially requested with the authority prescription, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be made by telephone.

**Authority required**

Second and subsequent applications for continuing treatment

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.

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.

No applications for increased repeats will be authorised.

### eltrombopag 25 mg tablet, 28

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### eltrombopag 50 mg tablet, 28

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**ROMIPLOSTIM**

**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-subsidised treatment, 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

HOBART TAS 7001

Further prescribing information is on the Medicare Australia website at www.medicareaustralia.gov.au.

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.

Special Pricing Arrangements apply.

<table>
<thead>
<tr>
<th>romiplostim 250 microgram injection, 1 x 250 microgram vial</th>
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<table>
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<th>romiplostim 500 microgram injection, 1 x 500 microgram vial</th>
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<td>9698K Max Qty Packs</td>
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** ANTIANEMIC PREPARATIONS **

** OTHER ANTIANEMIC PREPARATIONS **

Other antianemic preparations

** DARBEPOETIN ALFA **

Authority required (STREAMLINED) 3334

Treatment of anaemia requiring transfusion, defined as a haemoglobin level of less than 100 g per L, where intrinsic renal disease, as assessed by a nephrologist, is the primary cause of the anaemia

darbepoetin alfa 10 microgram/0.4 mL injection, 4 x 0.4 mL syringes

<table>
<thead>
<tr>
<th>darbepoetin alfa 10 microgram/0.4 mL injection, 4 x 0.4 mL syringes</th>
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### Schedule of Pharmaceutical Benefits

#### Darbepoetin Alfa

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### EPOETIN ALFA

**Authority required (STREAMLINED)**

**3334**

Treatment of anaemia requiring transfusion, defined as a haemoglobin level of less than 100 g per L, where intrinsic renal disease, as assessed by a nephrologist, is the primary cause of the anaemia.
### EPOETIN ALFA

**BLOOD AND BLOOD FORMING ORGANS**

<table>
<thead>
<tr>
<th>Product Description</th>
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<th>Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>Brand Name and Manufacturer</th>
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<td>Eprex 1000 [JC]</td>
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<td>Epoetin alfa 3000 international units/0.3 mL injection, 6 x 0.3 mL syringes</td>
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**EPOETIN BETA**

*Authority required (STREAMLINED)*

3334

Treatment of anaemia requiring transfusion, defined as a haemoglobin level of less than 100 g per L, where intrinsic renal disease, as assessed by a nephrologist, is the primary cause of the anaemia.

<table>
<thead>
<tr>
<th>Product Description</th>
<th>Max Qty</th>
<th>Packs</th>
<th>No. of Rpts</th>
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<th>DPMQ $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
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</table>
### Schedule of Pharmaceutical Benefits

**EPOETIN LAMBDA**

**Authority required (STREAMLINED)**

3334

Treatment of anaemia requiring transfusion, defined as a haemoglobin level of less than 100 g per L, where intrinsic renal disease, as assessed by a nephrologist, is the primary cause of the anaemia.

**Note**

Epoetin lambda should only be administered by the intravenous route.

<table>
<thead>
<tr>
<th><strong>EPOETIN LAMBDA</strong></th>
<th><strong>Authority required (STREAMLINED)</strong></th>
<th><strong>3334</strong></th>
<th><strong>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</strong></th>
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<tr>
<td><strong>EPOETIN LAMBDA</strong></td>
<td><strong>Authority required (STREAMLINED)</strong></td>
<td><strong>3334</strong></td>
<td><strong>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</strong></td>
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<td><strong>3334</strong></td>
<td><strong>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</strong></td>
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<td><strong>3334</strong></td>
<td><strong>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</strong></td>
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<td><strong>3334</strong></td>
<td><strong>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</strong></td>
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<td><strong>EPOETIN LAMBDA</strong></td>
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<td><strong>3334</strong></td>
<td><strong>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</strong></td>
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<td><strong>3334</strong></td>
<td><strong>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</strong></td>
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</table>

**METHOXY POLYETHYLENE GLYCOL-EPOETIN BETA**

**Authority required (STREAMLINED)**

3334

Treatment of anaemia requiring transfusion, defined as a haemoglobin level of less than 100 g per L, where intrinsic renal disease, as assessed by a nephrologist, is the primary cause of the anaemia.

**Note**

Methoxy polyethylene glycol-eopoetin beta should only be administered by the intravenous route.

### Schedule of Pharmaceutical Benefits

**HSD (Public)**
CARDIOVASCULAR SYSTEM

methoxy polyethylene glycol-epoetin beta 200 microgram/0.3 mL injection, 1 x 0.3 mL syringe

<table>
<thead>
<tr>
<th>5799F</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
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methoxy polyethylene glycol-epoetin beta 30 microgram/0.3 mL injection, 1 x 0.3 mL syringe

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methoxy polyethylene glycol-epoetin beta 300 microgram/0.6 mL injection, 1 x 0.6 mL syringe

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methoxy polyethylene glycol-epoetin beta 75 microgram/0.3 mL injection, 1 x 0.3 mL syringe

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</table>

CARDIOVASCULAR SYSTEM

ANTIHYPERTENSIVES

OTHER ANTIHYPERTENSIVES

Antihypertensives for pulmonary arterial hypertension

AMBRISSENTAN

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.

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 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.

**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, **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
HSD (Public)

CARDIOVASCULAR SYSTEM

(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 of an assessment required must cease PBS-subsidised therapy with this agent, AND 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.

**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 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 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, 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.

**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.

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.
(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 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.

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.

**Authority required**

Pulmonary arterial hypertension (PAH)  
Treatment Phase: Initial 2 (new patients)

**Clinical criteria:**

Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, AND  
Patient must have been assessed by a physician at a designated hospital, AND  
Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH, and a mean right atrial pressure of greater than 8 mmHg, as measured by right heart catheterisation (RHC); OR  
Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH, with right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds; OR  
Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease and a mean right atrial pressure greater than 8 mmHg, as measured by RHC; OR  
Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease with right ventricular function assessed by ECHO where a RHC cannot be performed on clinical grounds; OR
Patient must have WHO Functional Class IV idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH; OR
Patient must have WHO Functional Class IV pulmonary arterial hypertension secondary to connective tissue disease; OR
Patient must have WHO Functional Class III or IV pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology), AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:
(1) two completed authority prescription forms; and
(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
   (i) RHC composite assessment; and
   (ii) ECHO composite assessment; and
   (iii) 6 Minute Walk Test (6MWT); and
(3) a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditable pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:
(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or
(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:
The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:
(1) RHC plus ECHO composite assessments;
(2) RHC composite assessment plus 6MWT;
(3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:
(1) ECHO composite assessment plus 6MWT;
(2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Approvals for the first authority prescription will be limited to 1 month of therapy with the 62.5 mg strength tablet, with the quantity approved based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information. No repeats will be authorised for this prescription.

The second authority prescription may be written for either the 62.5 mg tablet or the 125 mg tablet strengths. Approvals for the second authority prescription will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.
PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

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 submitted. 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.

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.

**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
Pulmonary arterial hypertension (PAH)

Clinical criteria:
Patient must have received approval for initial PBS-subsidised treatment with this agent, AND
Patient must have been assessed by a physician from a designated hospital to have achieved a response to their most recent course of treatment with this agent, AND
The treatment must be the sole PBS-subsidised PAH agent for this condition.
Applications for authorisation must be in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
(i) RHC composite assessment; and
(ii) ECHO composite assessment; and
(iii) 6 Minute Walk Test (6MWT).
Test requirements to establish response to treatment for continuation of treatment are as follows:
The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:
(1) RHC plus ECHO composite assessments plus 6MWT;
(2) RHC plus ECHO composite assessments;
(3) RHC composite assessment plus 6MWT;
(4) ECHO composite assessment plus 6MWT;
(5) RHC composite assessment only;
(6) ECHO composite assessment only.
The results of the same tests as conducted at baseline should be provided with each written continuing treatment application (i.e., every 6 months), except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application. The test results provided with the application for continuing treatment must be no more than 2 months old at the time of application.
Response to a PAH agent is defined as follows:
For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.
For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.
For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.
For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.
The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information. A maximum of 5 repeats will be authorised.
The assessment of the patient's response to the first and subsequent 6 month courses of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated. Applications for continuing treatment with a PAH agent should be made prior to the completion of the 6 month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician.
Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.
The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.
PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Note
Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of 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
bosentan 125 mg tablet, 60

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**BOSENTAN**

*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.

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 (new patients)

**Clinical criteria:**

Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, **AND**

Patient must have been assessed by a physician at a designated hospital, **AND**

Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or heritable PAH; **OR**

Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease, **AND**

Patient must have a mean right atrial pressure of 8 mmHg or less as measured by right heart catheterisation (RHC); **OR**

Patient must have right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds, **AND**

Patient must have failed to respond to 6 or more weeks of appropriate vasodilator treatment unless intolerance or a contraindication to such treatment exists, **AND**

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) 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.

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.

**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 secondary to connective tissue disease; **OR**
- Patient must have WHO Functional Class 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.

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.

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.

Approval 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.

Applications for authorisation must be in writing and must include:
- two completed authority prescription forms; and
- supporting information form; and
- the results of the patient's response to treatment with their last course of PBS-subsidised PAH agent.

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 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.

Patients who have not failed prior PBS-subsidised treatment with this 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.

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.

**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.

**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

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.

**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 hereditary 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:
   - (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.

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.

**Authority required**

### Pulmonary arterial hypertension (PAH)

**Treatment Phase: Initial 2** (change or re-commencement of therapy for all patients)

**Clinical criteria:**

Patient must have idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or 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 IV idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or heritable 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 heritable 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 tobosentan 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.

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

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 physicist 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 physicist 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 physicist 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 physicist 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

Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

Pharmaceutical benefits that have the form epoprostenol sodium powder for I.V. infusion 500 microgram vial are equivalent for the purposes of substitution.

Pharmaceutical benefits that have the form epoprostenol sodium powder for I.V. infusion 1.5 mg vial are equivalent for the purposes of substitution.

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

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Pharmaceutical benefits that have the form epoprostenol sodium powder for I.V. infusion 1.5 mg vial are equivalent for the purposes of substitution.

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

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Pharmaceutical benefits that have the form epoprostenol sodium powder for I.V. infusion 1.5 mg vial are equivalent for the purposes of substitution.

The term ‘PAH agents’ refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Note

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

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

Applications for authority to prescribe should be forwarded to:

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Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

Pharmaceutical benefits that have the form epoprostenol sodium powder for I.V. infusion 500 microgram vial are equivalent for the purposes of substitution.

Pharmaceutical benefits that have the form epoprostenol sodium powder for I.V. infusion 1.5 mg vial are equivalent for the purposes of substitution.
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, 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.

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 (new patients)
Clinical criteria:
- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, AND
- Patient must have been assessed by a physician at a designated hospital, AND
- Patient must have WHO Functional Class III drug-induced PAH and a mean right atrial pressure greater than 8 mmHg, as measured by right heart catheterisation (RHC); OR
- Patient must have WHO Functional Class III drug-induced PAH with right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds; OR
- Patient must have WHO Functional Class IV idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH; OR
- Patient must have WHO Functional Class IV pulmonary arterial hypertension secondary to connective tissue disease; OR
- Patient must have WHO Functional Class IV drug-induced PAH, AND
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:
1. A completed authority prescription form; and
2. A completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
   i. RHC composite assessment; and
   ii. ECHO composite assessment; and
   iii. 6 Minute Walk Test (6MWT); and
3. A signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditable pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger’s physiology) are defined as follows:
- Mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or
- 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.

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 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 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.

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 or Initial 2 (new patients) or Initial 3 (change or re-commencement of therapy for all patients) or Continuing treatment (all patients) – balance of supply

**Clinical criteria:**

Patient must have received insufficient therapy with this agent under the Initial 1 (new patients) restriction to complete a maximum of six months of treatment; OR

Patient must have received insufficient therapy with this agent under the Initial 2 (new patients) restriction to complete a maximum of six months of treatment; OR

Patient must have received insufficient therapy with this agent under the Initial 3 (change or re-commencement of therapy for all patients) restriction to complete a maximum of six months of treatment; OR

Patient must have received insufficient therapy with this agent under the Continuing treatment (all patients) restriction to complete a maximum of six months of treatment, **AND**

The treatment must be the sole PBS-subsidised PAH agent for this condition, **AND**

The treatment must provide no more than the balance of up to six months treatment available under the above restrictions.

**Note**

Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authorisation under this criterion should be forwarded to:

Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826

HOBART TAS 7001

**Authority required**
Pulmonary arterial hypertension (PAH)

Treatment Phase: Continuing treatment (all patients)

**Clinical criteria:**
Patient must have received approval for initial PBS-subsidised treatment with this agent, **AND**
Patient must have been assessed by a physician from a designated hospital to have achieved a response to their most recent course of treatment with this agent, **AND**
The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
(i) RHC composite assessment; and
(ii) ECHO composite assessment; and
(iii) 6 Minute Walk Test (6MWT).

Test requirements to establish response to treatment for continuation of treatment are as follows:
The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:
(1) RHC plus ECHO composite assessments plus 6MWT;
(2) RHC plus ECHO composite assessments;
(3) RHC composite assessment plus 6MWT;
(4) ECHO composite assessment plus 6MWT;
(5) RHC composite assessment only;
(6) ECHO composite assessment only.

The results of the same tests as conducted at baseline should be provided with each written continuing treatment application (i.e., every 6 months), except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application.
The test results provided with the application for continuing treatment must be no more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:
For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.
For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.
For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.
For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.
The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.
A maximum of 5 repeats will be authorised.
The assessment of the patient's response to the first and subsequent 6 month courses of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.
Applications for continuing treatment with a PAH agent should be made prior to the completion of the 6 month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician.
Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.
The term ‘PAH agents’ refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.
PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

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

HOBART TAS 7001
Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.
Special Pricing Arrangements apply.
**MACITENTAN**

**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.

**Authority required**
Pulmonary arterial hypertension (PAH)
Treatment Phase: Initial 1 (new patients)

**Clinical criteria:**
Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, AND
Patient must have been assessed by a physician at a designated hospital, AND
Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or heritable PAH; OR
Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease, AND
Patient must have a mean right atrial pressure of 8 mmHg or less as measured by right heart catheterisation (RHC); OR
Patient must have right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds, AND
Patient must have failed to respond to 6 or more weeks of appropriate vasodilator treatment unless intolerance or a contraindication to such treatment exists, AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
(i) RHC composite assessment; and
(ii) ECHO composite assessment; and
(iii) 6 Minute Walk Test (6MWT); and
(3) a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, heritable pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:
(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or
(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:
The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:
(1) RHC plus ECHO composite assessments;
(2) RHC composite assessment plus 6MWT;
(3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:
(1) ECHO composite assessment plus 6MWT;
(2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Details of prior vasodilator treatment, including the dose and duration of treatment, must be provided at the time of application. Where the patient has an adverse event to a vasodilator or where vasodilator treatment is contraindicated, details of the nature of the adverse event or contraindication according to the Therapeutic Goods Administration (TGA) approved Product Information must also be provided with the 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.

**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:

1. a completed authority prescription form; and
2. a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
   1. (i) RHC composite assessment; and
   2. (ii) ECHO composite assessment; and
   3. (iii) 6 Minute Walk Test (6MWT); and

3. a signed patient acknowledgement.

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.

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.

**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 heritable 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 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 heritable 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 for 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.

**Authority required**

**Pulmonary arterial hypertension (PAH)**

**Treatment Phase:** Initial 1 or Initial 2 (new patients) or Initial 3 (change or re-commencement of therapy for all patients) or Continuing treatment (all patients) – balance of supply

**Clinical criteria:**

Patient must have received insufficient therapy with this agent under the Initial 1 (new patients) restriction to complete a maximum of six months of treatment; OR

Patient must have received insufficient therapy with this agent under the Initial 2 (new patients) restriction to complete a maximum of six months of treatment; OR
Patient must have received insufficient therapy with this agent under the Initial 3 (change or re-commencement of therapy for all patients) restriction to complete a maximum of six months of treatment; OR Patient must have received insufficient therapy with this agent under the Continuing treatment (all patients) restriction to complete a maximum of six months of treatment, **AND** The treatment must be the sole PBS-subsidised PAH agent for this condition, **AND** The treatment must provide no more than the balance of up to six months treatment available under the above restrictions.

**Note**
Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written applications for authorisation under this criterion should be forwarded to: Department of Human Services Prior Written Approval of Complex Drugs Reply Paid 9826 GPO Box 9826

HOBART TAS 7001

**Authority required**
Pulmonary arterial hypertension (PAH)
Treatment Phase: Continuing treatment (all patients)

**Clinical criteria:**
Patient must have received approval for initial PBS-subsidised treatment with this agent, **AND** Patient must have been assessed by a physician from a designated hospital to have achieved a response to their most recent course of treatment with this agent, **AND** The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:
1. a completed authority prescription form; and
2. a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
   i. RHC composite assessment; and
   ii. ECHO composite assessment; and
   iii. 6 Minute Walk Test (6MWT).

Test requirements to establish response to treatment for continuation of treatment are as follows:
The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:

1. RHC plus ECHO composite assessments plus 6MWT;
2. RHC plus ECHO composite assessments;
3. RHC composite assessment plus 6MWT;
4. ECHO composite assessment plus 6MWT;
5. RHC composite assessment only;
6. ECHO composite assessment only.

The results of the same tests as conducted at baseline should be provided with each written continuing treatment application (i.e., every 6 months), except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application.

The test results provided with the application for continuing treatment must be no more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:
For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.
For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.
For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.
For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.
The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

The assessment of the patient’s response to the first and subsequent 6 month courses of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.
Applications for continuing treatment with a PAH agent should be made prior to the completion of the 6 month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician.
Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term ‘PAH agents’ refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.
PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

**Note**

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826

HOBART TAS 7001

Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

### 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**

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 catheterization (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.

**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) a completed authority prescription form; and
2. (a) 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) 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. (i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or
2. (ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

1. (a) RHC plus ECHO composite assessments;
2. (b) RHC composite assessment plus 6MWT;
3. (c) 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. (a) ECHO composite assessment plus 6MWT;
Pulmonary arterial hypertension (PAH)

Authority required

Applications for patients who wish to swap to an alternate PAH agent should be accompanied by the previously approved 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.

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.
Treatment Phase: Initial 1 or Initial 2 (new patients) or Initial 3 (change or re-commencement of therapy for all patients) or Continuing treatment (all patients) – balance of supply

Clinical criteria:
Patient must have received insufficient therapy with this agent under the Initial 1 (new patients) restriction to complete a maximum of six months of treatment; OR
Patient must have received insufficient therapy with this agent under the Initial 2 (new patients) restriction to complete a maximum of six months of treatment; OR
Patient must have received insufficient therapy with this agent under the Initial 3 (change or re-commencement of therapy for all patients) restriction to complete a maximum of six months of treatment; OR
Patient must have received insufficient therapy with this agent under the Continuing treatment (all patients) restriction to complete a maximum of six months of treatment, AND

The treatment must be the sole PBS-subsidised PAH agent for this condition, AND

The treatment must provide no more than the balance of up to six months treatment available under the above restrictions.

Note
Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written applications for authorisation under this criterion should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826

HOBART TAS 7001

Authority required
Pulmonary arterial hypertension (PAH)
Treatment Phase: Continuing treatment (all patients)

Clinical criteria:
Patient must have received approval for initial PBS-subsidised treatment with this agent, AND
Patient must have been assessed by a physician from a designated hospital to have achieved a response to their most recent course of treatment with this agent, AND
The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
(i) RHC composite assessment; and
(ii) ECHO composite assessment; and
(iii) 6 Minute Walk Test (6MWT).

Test requirements to establish response to treatment for continuation of treatment are as follows:
The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:
(1) RHC plus ECHO composite assessments plus 6MWT;
(2) RHC plus ECHO composite assessments;
(3) RHC composite assessment plus 6MWT;
(4) ECHO composite assessment plus 6MWT;
(5) RHC composite assessment only;
(6) ECHO composite assessment only.

The results of the same tests as conducted at baseline should be provided with each written continuing treatment application (i.e., every 6 months), except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application.

The test results provided with the application for continuing treatment must be no more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:
For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.
For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.
For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.
For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.
A maximum of 5 repeats will be authorised.
The assessment of the patient’s response to the first and subsequent 6 month courses of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated. Applications for continuing treatment with a PAH agent should be made prior to the completion of the 6 month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term ‘PAH agents’ refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Note

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

### sildenafil 20 mg tablet, 90

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#### TADALAFIL

**Authority required**

Pulmonary arterial hypertension (PAH)

**Treatment Phase: Initial 1 (new patients)**

**Clinical criteria:**

Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, **AND**

Patient must have been assessed by a physician at a designated hospital, **AND**

Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (IPAH) or anorexigen-induced PAH or heritable PAH; **OR**

Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease, **AND**

Patient must have a mean left atrial pressure of 8 mmHg or less as measured by right heart catheterisation (RHC); **OR**

Patient must have right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds, **AND**

Patient must have failed to respond to 6 or more weeks of appropriate vasodilator treatment unless intolerance or a contraindication to such treatment exists, **AND**

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6 Minute Walk Test (6MWT); and

(3) a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, heritable pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger’s physiology) are defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient’s baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:
Test requirements to establish baseline for initiation of treatment are as follows:

(1) RHC 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.

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.

**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 hereditary 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 hereditary 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, 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:**

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 at least 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 treatment must be the sole 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.

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.

**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 hereditary 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 hereditary 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, 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:
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.

**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 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.

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 respond to their current treatment, 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.

**Authority required**
Pulmonary arterial hypertension (PAH)
**Clinical criteria:**
- Patient must have received insufficient therapy with this agent under the Initial 1 (new patients) restriction to complete a maximum of six months of treatment; OR
- Patient must have received insufficient therapy with this agent under the Initial 2 (new patients) restriction to complete a maximum of six months of treatment; OR
- Patient must have received insufficient therapy with this agent under the Initial 3 (change or re-commencement of therapy for all patients) restriction to complete a maximum of six months of treatment; OR
- Patient must have received insufficient therapy with this agent under the Continuing treatment (all patients) restriction to complete a maximum of six months of treatment. **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition, **AND**
- The treatment must provide no more than the balance of up to six months treatment available under the above restrictions.

**Note**
Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written applications for authorisation under this criterion should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

**Authority required**
Pulmonary arterial hypertension (PAH)
**Clinical criteria:**
- Patient must have received approval for initial PBS-subsidised treatment with this agent, **AND**
- Patient must have been assessed by a physician from a designated hospital to have achieved a response to their most recent course of treatment with this agent, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:
1. a completed authority prescription form; and
2. a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:
   i. RHC composite assessment; and
   ii. ECHO composite assessment; and
   iii. 6 Minute Walk Test (6MWT).

Test requirements to establish response to treatment for continuation of treatment are as follows:
The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:
1. RHC plus ECHO composite assessments plus 6MWT;
2. RHC plus ECHO composite assessments;
3. RHC composite assessment plus 6MWT;
4. ECHO composite assessment plus 6MWT;
5. RHC composite assessment only;
6. ECHO composite assessment only.

The results of the same tests as conducted at baseline should be provided with each written continuing treatment application (i.e., every 6 months), except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application.
The test results provided with the application for continuing treatment must be no more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:
For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.
For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.
For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.
For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

The assessment of the patient’s response to the first and subsequent 6 month courses of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Applications for continuing treatment with a PAH agent should be made prior to the completion of the 6 month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term ‘PAH agents’ refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of 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.

### Schedule of Pharmaceutical Benefits

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#### SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS

#### PITUITARY AND HYPOTHALAMIC HORMONES AND ANALOOGUES

### HYPOTHALAMIC HORMONES

#### Somatostatin and analogues

### LANREOTIDE

**Authority required (STREAMLINED)**

#### 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 if IGF1 is not lower after 3 months of treatment.

*lanreotide 30 mg injection: modified release [1 x 30 mg vial] (&) inert substance diluent [1 x 2 mL ampoule], 1 pack*

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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.

lanreotide 120 mg injection, 1 syringe
5779E
Max Qty Packs No. of Rpts Premium $ DPMQ $ Brand Name and Manufacturer
2 5 .. *4480.00 Somatuline Autogel [IS]

lanreotide 60 mg injection, 1 syringe
5777C
Max Qty Packs No. of Rpts Premium $ DPMQ $ Brand Name and Manufacturer
2 5 .. *2690.00 Somatuline Autogel [IS]

lanreotide 90 mg injection, 1 syringe
5778D
Max Qty Packs No. of Rpts Premium $ DPMQ $ Brand Name and Manufacturer
2 5 .. *3580.00 Somatuline Autogel [IS]

OCTREOTIDE

Authority required (STREAMLINED)
3407
Active acromegaly in a patient with persistent elevation of mean growth hormone levels of greater than 2.5 micrograms per litre AND
(a) after failure of other therapy including dopamine agonists; or
(b) as interim treatment while awaiting the effects of radiotherapy and where treatment with dopamine agonists has failed; or
(c) if the patient is unfit for or unwilling to undergo surgery and where radiotherapy is contraindicated.
In a patient treated with radiotherapy, treatment must cease if there is biochemical evidence of remission (normal IGF1) after octreotide has been withdrawn for at least 4 weeks. Octreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission.
Treatment must cease if IGF1 is not lower after 3 months treatment at a dose of 100 micrograms 3 times daily

Authority required (STREAMLINED)
3408
Functional carcinoid tumour or vasoactive intestinal peptide secreting tumour (VIPoma) causing intractable symptoms. The patient must have experienced on average over 1 week, 3 or more episodes per day of 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.

octreotide 100 microgram/mL injection, 5 x 1 mL ampoules
9509L
Max Qty Packs No. of Rpts Premium $ DPMQ $ Brand Name and Manufacturer
18 11 .. *1236.42 * Hospira Pty Limited [HH] * Octreotide MaxRx [GQ]
### 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.

**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.

**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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### CALCIUM HOMEOSTASIS

**ANTI-PARATHYROID AGENTS**

*Other anti-parathyroid agents*

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### CINACALCET

**Authority required (STREAMLINED)**

**3233**
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)**

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.

Special Pricing Arrangements apply.

cinacalcet 30 mg tablet, 28

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**ANTIINFECTIVES FOR SYSTEMIC USE**

**ANTIBACTERIALS FOR SYSTEMIC USE**

**MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS**

**Macrolides**

**AZITHROMYCIN**

**Authority required (STREAMLINED)**

Prophylaxis against Mycobacterium avium complex infections in HIV-positive patients with CD4 cell counts of less than 75 per cubic millimetre.

azithromycin 600 mg tablet, 8

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**CLARITHROMYCIN**

**Authority required (STREAMLINED)**

Treatment of Mycobacterium avium complex infections.

clarithromycin 250 mg tablet, 100

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clarithromycin 500 mg tablet, 100

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**ANTIMYCOBACTERIALS**

**DRUGS FOR TREATMENT OF TUBERCULOSIS**

**Antibiotics**
RIFABUTIN

**Authority required (STREAMLINED)**

3415
Treatment of Mycobacterium avium complex infections in HIV-positive patients

**Authority required (STREAMLINED)**

3317
Prophylaxis against Mycobacterium avium complex infections in HIV-positive patients with CD4 cell counts of less than 75 per cubic millimetre

rifabutin 150 mg capsule, 30

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ANTIVIRALS FOR SYSTEMIC USE

DIRECT ACTING ANTIVIRALS

Nucleosides and nucleotides excl. reverse transcriptase inhibitors

GANCICLOVIR

**Authority required (STREAMLINED)**

3379
Cytomegalovirus retinitis in severely immunocompromised patients

**Authority required (STREAMLINED)**

3380
Prophylaxis of cytomegalovirus disease in bone marrow transplant patients at risk of cytomegalovirus disease

**Authority required (STREAMLINED)**

3381
Prophylaxis of cytomegalovirus disease in solid organ transplant patients at risk of cytomegalovirus disease

ganciclovir 500 mg injection, 5 x 500 mg vials

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VALACICLOVIR

**Authority required (STREAMLINED)**

3419
Prophylaxis of cytomegalovirus (CMV) infection and disease following renal transplantation in patients at risk of CMV disease

valaciclovir 500 mg tablet, 100

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<td>* Valaciclovir RBX [RA]</td>
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VALGANCICLOVIR

**Authority required (STREAMLINED)**

3420
Cytomegalovirus retinitis in patients with acquired immunodeficiency syndrome

**Authority required (STREAMLINED)**

3421
Prophylaxis of cytomegalovirus infection and disease in solid organ transplant patients at risk of cytomegalovirus disease

valganciclovir 450 mg tablet, 60

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valganciclovir 50 mg/mL oral liquid: powder for, 100 mL

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Phosphonic acid derivatives

FOSCARNET

**Authority required (STREAMLINED)**

3322
Treatment of cytomegalovirus retinitis in patients with AIDS

**Authority required (STREAMLINED)**

3378
Treatment of aciclovir-resistant herpes simplex virus infection in immunocompromised patients with HIV infection
**ANTIINFECTIVES FOR SYSTEMIC USE**

**FOSCARNET SODIUM I.V. infusion 24 mg per mL, 250 mL bottle, 5747L**

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**Protease inhibitors**

- **ATAZANAVIR**

  **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.

  **atazanavir 150 mg capsule, 60**

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  **atazanavir 200 mg capsule, 60**

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  **atazanavir 300 mg capsule, 30**

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- **BOCEPREVIR**

  **Authority required (STREAMLINED)**

  **4182**
  
  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 who were partial responders or relapers to the prior course of interferon based therapy for hepatitis C; **OR**
  The treatment must be limited to a maximum duration of 44 weeks in patients without hepatic cirrhosis who were null responders to the prior course of interferon based therapy for hepatitis C; **OR**
  The treatment must be limited to a maximum duration of 44 weeks for all patients with hepatic cirrhosis, **AND**
  The treatment must cease after the first 8 weeks of boceprevir treatment if plasma HCV RNA is detectable by an HCV RNA qualitative assay at treatment week 12, **AND**
  The treatment must cease after the first 20 weeks of boceprevir treatment if plasma HCV RNA is detectable by an HCV RNA qualitative assay at treatment week 24.

  **Population criteria:**
  
  Patient must be 18 years or older, **AND**
  Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

  **Treatment criteria:**
  
  Must be treated in an accredited treatment centre.
  
  Chronic genotype 1 hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.
  
  Patients who have received prior treatment with an NS3/4A protease inhibitor are not eligible to receive PBS-subsidised boceprevir, except where the patient has developed an intolerance to the other NS3/4A protease inhibitor of a severity necessitating permanent treatment withdrawal. Details of the intolerance must be documented in the patient's medical records.
  
  For patients without hepatic cirrhosis who were partial responders or relapers to the prior course of interferon based therapy, a maximum of 7 repeats may be prescribed.
  
  For patients without hepatic cirrhosis who were null responders to the prior course of interferon based therapy, a maximum of 10 repeats may be prescribed.
For patients with hepatic cirrhosis, a maximum of 10 repeats may be prescribed.

**Authority required (STREAMLINED)**

**4202**

Chronic genotype 1 hepatitis C infection

**Clinical criteria:**
- Patient must have compensated liver disease, **AND**
- Patient must not have received prior interferon alfa or peginterferon alfa treatment for hepatitis C, **AND**
- The treatment must be in combination with peginterferon alfa and ribavirin, **AND**
- The treatment must be limited to a maximum duration of 24 weeks in patients without hepatic cirrhosis; **OR**
- The treatment must be limited to a maximum duration of 44 weeks in patients with hepatic cirrhosis, **AND**
- The treatment must cease after the first 20 weeks of boceprevir treatment if plasma HCV RNA is detectable by an HCV RNA qualitative assay at treatment week 24.

**Population criteria:**
- Patient must be 18 years or older, **AND**
- Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

**Treatment criteria:**
- Must be treated in an accredited treatment centre.
- Evidence of chronic genotype 1 hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient’s medical records.
- Patients who have received prior treatment with an NS3/4A protease inhibitor are not eligible to receive PBS-subsidised boceprevir, except where the patient has developed an intolerance to the other NS3/4A protease inhibitor of a severity necessitating permanent treatment withdrawal. Details of the intolerance must be documented in the patient’s medical records.

For patients without hepatic cirrhosis, a maximum of 5 repeats may be prescribed. For patients with hepatic cirrhosis, a maximum of 10 repeats may be prescribed.

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

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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**Boceprevir 200 mg capsule, 336 capsules**

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**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.

**Darunavir 800 mg tablet, 30**

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**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.
### Fosamprenavir

**Authority required (STREAMLINED)**

**4512**

**HIV infection**

**Clinical criteria:**
- Patient must be antiretroviral treatment naive, **AND**
- The treatment must be in combination with other antiretroviral agents.

**4454**

**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.

<table>
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### Indinavir

**Authority required (STREAMLINED)**

**4512**

**HIV infection**

**Clinical criteria:**
- Patient must be antiretroviral treatment naive, **AND**
- The treatment must be in combination with other antiretroviral agents.

**4454**

**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.

<table>
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### Ritonavir

**Authority required (STREAMLINED)**

**4512**

**HIV infection**

**Clinical criteria:**
- Patient must be antiretroviral treatment naive, **AND**
- The treatment must be in combination with other antiretroviral agents.

**4454**

**HIV infection**

**Clinical criteria:**
- The treatment must be in combination with other antiretroviral agents.
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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**SAQUINAVIR**

**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.

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**SIMEPREVIR**

**Authority required (STREAMLINED)**

**4758**

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 12 weeks, AND
The treatment must cease if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is 25 IU/mL or greater.

**Population criteria:**

Patient must be aged 18 years or older, AND
Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

**Treatment criteria:**

Must be treated in an accredited treatment centre.

Evidence of chronic genotype 1 hepatitis C infection (repeatedly anti-HCV positive and HCV RNA positive) must be documented in the patient’s medical records.

Patients who have received prior treatment with an NS3/4A protease inhibitor are not eligible to receive PBS-subsidised simprevir, except where the patient has developed an intolerance to the other NS3/4A protease inhibitor of a severity necessitating permanent treatment withdrawal. Details of the intolerance must be documented in the patient’s medical records.

**Authority required (STREAMLINED)**

**4759**

Chronic genotype 1 hepatitis C infection

**Clinical criteria:**

Patient must have compensated liver disease, AND
Patient must have received prior treatment with interferon alfa or peginterferon alfa for hepatitis C, AND
The treatment must be in combination with peginterferon alfa and ribavirin, AND
The treatment must be limited to a maximum duration of 12 weeks, AND
The treatment must cease if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is 25 IU/mL or greater.

**Population criteria:**

Patient must be 18 years or older, AND
Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

**Treatment criteria:**
- Must be treated in an accredited treatment centre.
- Evidence of chronic genotype 1 hepatitis C infection (repeatedly anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.
- Patients who have received prior treatment with an NS3/4A protease inhibitor are not eligible to receive PBS-subsidised simeprevir, except where the patient has developed an intolerance to the other NS3/4A protease inhibitor of a severity necessitating permanent treatment withdrawal. Details of the intolerance must be documented in the patient's medical records.

**Note**
- No increase in the maximum quantity or number of units may be authorised.
- No increase in the maximum number of repeats may be authorised.
- Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:
  - (a) a nurse educator/counsellor for patients; and
  - (b) 24-hour access by patients to medical advice; and
  - (c) an established liver clinic.

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**simeprevir sodium 150 mg capsule, 7**

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**TELAPREVIR**

**Authority required (STREAMLINED)**

**4186**

Chronic genotype 1 hepatitis C infection

**Clinical criteria:**
- Patient must have compensated liver disease, **AND**
- Patient must not have received prior treatment with interferon alfa or peginterferon alfa for hepatitis C, **AND**
- The treatment must be in combination with peginterferon alfa and ribavirin, **AND**
- The treatment must be limited to a maximum duration of 12 weeks, **AND**
- The treatment must cease if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is greater than 1000 IU/mL.

**Population criteria:**
- Patient must be 18 years or older, **AND**
- Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

**Treatment criteria:**
- Must be treated in an accredited treatment centre.
- Evidence of chronic genotype 1 hepatitis C infection (repeatedly anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.
- Patients who have received prior treatment with an NS3/4A protease inhibitor are not eligible to receive PBS-subsidised telaprevir, except where the patient has developed an intolerance to the other NS3/4A protease inhibitor of a severity necessitating permanent treatment withdrawal. Details of the intolerance must be documented in the patient's medical records.

**Authority required (STREAMLINED)**

**4191**

Chronic genotype 1 hepatitis C infection

**Clinical criteria:**
- Patient must have compensated liver disease, **AND**
- Patient must have received prior treatment with interferon alfa or peginterferon alfa for hepatitis C, **AND**
- The treatment must be in combination with peginterferon alfa and ribavirin, **AND**
- The treatment must be limited to a maximum duration of 12 weeks, **AND**
- The treatment must cease if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is greater than 1000 IU/mL.

**Population criteria:**
- Patient must be 18 years or older, **AND**
- Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

**Treatment criteria:**
- Must be treated in an accredited treatment centre.
- Evidence of chronic genotype 1 hepatitis C infection (repeatedly anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.
- Patients who have received prior treatment with an NS3/4A protease inhibitor are not eligible to receive PBS-subsidised telaprevir, except where the patient has developed an intolerance to the other NS3/4A protease inhibitor of a severity
necessitating permanent treatment withdrawal. Details of the intolerance must be documented in the patient’s medical records.

Note
No increase in the maximum quantity or number of units may be authorised.
No increase in the maximum number of repeats may be authorised.
Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:
(a) a nurse educator/counsellor for patients; and
(b) 24-hour access by patients to medical advice; and
(c) an established liver clinic.

telaprevir 375 mg tablet, 42

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**TIPRANAVIR**

**Authority required (STREAMLINED)**

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.

tipranavir 250 mg capsule, 120

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**Nucleoside and nucleotide reverse transcriptase inhibitors**

**ABACAVIR**

**Authority required (STREAMLINED)**

Treatment Phase: Initial

Clinical criteria:
Patient must be antiretroviral treatment naive, **AND**
The treatment must be in combination with other antiretroviral agents.

**Authority required (STREAMLINED)**

Treatment Phase: Continuing

Clinical criteria:
Patient must have previously received PBS-subsidised therapy for HIV infection, **AND**
The treatment must be in combination with other antiretroviral agents.

abacavir 20 mg/mL oral liquid, 240 mL

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abacavir 300 mg tablet, 60

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**ADEFOVIR DIPIVOXIL**

**Authority required (STREAMLINED)**

Chronic hepatitis B in a patient without cirrhosis who has failed antihepadnaviral therapy 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.
Chronic hepatitis B in a patient with cirrhosis who has failed ant_hepadnaviral 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 ant_hepadnaviral therapy.

**adeefovir dipivoxil 10 mg tablet, 30**

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<td>* Hepsera [GI]</td>
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**DIDANOSINE**

**Authority required (STREAMLINED)**

**4512**
HIV infection

**Treatment Phase: Initial**

**Clinical criteria:**

Patient must be antiretroviral treatment naive, **AND**
The treatment must be in combination with other antiretroviral agents.

**Authority required (STREAMLINED)**

**4454**
HIV infection

**Treatment Phase: Continuing**

**Clinical criteria:**

Patient must have previously received PBS-subsidised therapy for HIV infection, **AND**
The treatment must be in combination with other antiretroviral agents.

**didanosine 125 mg capsule: enteric, 30**

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**didanosine 200 mg capsule: enteric, 30**

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**didanosine 250 mg capsule: enteric, 30**

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**didanosine 400 mg capsule: enteric, 30**

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**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.

**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.

**emtricitabine 200 mg capsule, 30**

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### ENTECAVIR

**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.

**Note**

PBS-subsidised entecavir monohydrate must be used as monotherapy.

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<tr>
<th>entecavir monohydrate 500 microgram tablet, 30</th>
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### 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:

1. 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
2. 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 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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<th>entecavir monohydrate 1 mg tablet, 30</th>
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### 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.

**lamivudine 100 mg tablet, 28**

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**lamivudine 5 mg/mL oral liquid, 240 mL**

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† LAMIVUDINE

**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.

<table>
<thead>
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† 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:**
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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† 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.

telbivudine 600 mg tablet, 28

<table>
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**TENOFOVIR**

**Authority required (STREAMLINED)**

4512

HIV infection

**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, **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.

**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.

**Authority required (STREAMLINED)**

4490

Chronic hepatitis B

**Clinical criteria:**

Patient must not have cirrhosis, **AND**

Patient must have failed antiviral therapy, **AND**

Patient must have repeatedly elevated serum ALT levels while on concurrent antiviral therapy of greater than or equal to 6 months duration, in conjunction with documented chronic hepatitis B infection; **OR**

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 antiviral therapy, except in patients with evidence of poor compliance.

**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.

**ZIDOVUDINE**

**Authority required (STREAMLINED)**

4512
HIV infection
Treatment Phase: Initial

*Clinical criteria:*
Patient must be antiretroviral treatment naive, AND
The treatment must be in combination with other antiretroviral agents.

**Authority required (STREAMLINED)**

4454
HIV infection
Treatment Phase: Continuing

*Clinical criteria:*
Patient must have previously received PBS-subsidised therapy for HIV infection, AND
The treatment must be in combination with other antiretroviral agents.

**Non-nucleoside reverse transcriptase inhibitors**

**EFAVIRENZ**

**Authority required (STREAMLINED)**

4512
HIV infection
Treatment Phase: Initial

*Clinical criteria:*
Patient must be antiretroviral treatment naive, AND
The treatment must be in combination with other antiretroviral agents.

**Authority required (STREAMLINED)**

4454
HIV infection
Treatment Phase: Continuing

*Clinical criteria:*
Patient must have previously received PBS-subsidised therapy for HIV infection, AND
The treatment must be in combination with other antiretroviral agents.
**Efavirenz 600 mg tablet, 30**

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**ETRAVIRINE**

*Authority required (STREAMLINED)*

3597

Treatment of HIV infection, in addition to optimised background therapy in combination with other antiretroviral agents in an antiretroviral experienced patient who, after each of at least three different antiretroviral regimens that have included one drug from at least 3 different antiretroviral classes, has experienced virological failure or clinical failure or genotypic resistance.

Virological failure is defined as a viral load greater than 400 copies per mL on two consecutive occasions, while clinical failure is linked to emerging signs and symptoms of progressing HIV infection or treatment-limiting toxicity.

**Etravirine 200 mg tablet, 60**

<table>
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**NEVIRAPINE**

*Authority required (STREAMLINED)*

4526

HIV infection

Treatment Phase: Initial

Clinical criteria:
Patient must have been stabilised on nevirapine immediate release, AND
The treatment must be in combination with other antiretroviral agents.

*Authority required (STREAMLINED)*

4454

HIV infection

Treatment Phase: Continuing

Clinical criteria:
Patient must have previously received PBS-subsidised therapy for HIV infection, AND
The treatment must be in combination with other antiretroviral agents.

**Nevirapine 400 mg tablet: modified release, 30 tablets**

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**NEVIRAPINE**

*Authority required (STREAMLINED)*

4512

HIV infection

Treatment Phase: Initial

Clinical criteria:
Patient must be antiretroviral treatment naive, AND
The treatment must be in combination with other antiretroviral agents.

*Authority required (STREAMLINED)*

4454

HIV infection

Treatment Phase: Continuing

Clinical criteria:
Patient must have previously received PBS-subsidised therapy for HIV infection, AND
The treatment must be in combination with other antiretroviral agents.

**Nevirapine 10 mg/mL oral liquid, 240 mL**

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**Nevirapine 200 mg tablet, 60**

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**Rilpivirine**

*Authority required (STREAMLINED)*

4512

HIV infection
ANTIINFECTIVES FOR SYSTEMIC USE

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.

rilpivirine 25 mg tablet, 30
1173R

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<td>Edurant [JC]</td>
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</table>

**Antivirals for treatment of HIV infections, combinations**

- **ABACAVIR + LAMIVUDINE**

Authority required (STREAMLINED)
4527
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 (STREAMLINED)
4528
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.

abacavir 600 mg + lamivudine 300 mg tablet, 30
5603X

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- **ABACAVIR + LAMIVUDINE + ZIDOVUDINE**

Authority required (STREAMLINED)
4495
HIV infection
Treatment Phase: Initial

Clinical criteria:
Patient must be antiretroviral treatment naive.

Population criteria:
Patient must be aged 12 years or older, AND
Patient must weigh 40 kg or more.

Authority required (STREAMLINED)
4480
HIV infection
Treatment Phase: Continuing

Clinical criteria:
Patient must have previously received PBS-subsidised therapy for HIV infection.

Population criteria:
Patient must be aged 12 years or older, AND
Patient must weigh 40 kg or more.

abacavir 300 mg + lamivudine 150 mg + zidovudine 300 mg tablet, 60
5604Y

<table>
<thead>
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</table>
- **Dolutegravir + Abacavir + Lamivudine**
  Authority required (STREAMLINED)

  4495
  HIV infection
  Treatment Phase: Initial
  Clinical criteria:
  Patient must be antiretroviral treatment naive.
  Population criteria:
  Patient must be aged 12 years or older, **AND**
  Patient must weigh 40 kg or more.

  Authority required (STREAMLINED)

  dolutegravir 50 mg + abacavir 600 mg + lamivudine 300 mg tablet, 30

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- **Emtricitabine + Rilpivirine + Tenofovir**
  Authority required (STREAMLINED)

  4522
  HIV infection
  Treatment Phase: Initial
  Clinical criteria:
  Patient must be antiretroviral treatment naive.

  Authority required (STREAMLINED)

  emtricitabine 200 mg + rilpivirine 25 mg + tenofovir disoproxil fumarate 300 mg tablet, 30

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- **Lamivudine + Zidovudine**
  Authority required (STREAMLINED)

  4512
  HIV infection
  Treatment Phase: Initial
  Clinical criteria:
  Patient must be antiretroviral treatment naive, **AND**
The treatment must be in combination with other antiretroviral agents.

  Authority required (STREAMLINED)

  lamivudine 150 mg + zidovudine 300 mg tablet, 60

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- **Lopinavir + Ritonavir**
  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.

lopinavir 100 mg + ritonavir 25 mg tablet, 60

5790R

Max Qty Packs No. of Rpts Premium $ DPMQ $ Brand Name and Manufacturer
2 5 .. *342.50 Kaletra [VE]

lopinavir 200 mg + ritonavir 50 mg tablet, 120

5791T

Max Qty Packs No. of Rpts Premium $ DPMQ $ Brand Name and Manufacturer
2 5 .. *1370.00 Kaletra [VE]

lopinavir 400 mg/5 mL + ritonavir 100 mg/5 mL oral liquid, 60 mL

5789Q

Max Qty Packs No. of Rpts Premium $ DPMQ $ Brand Name and Manufacturer
10 5 .. *1290.00 Kaletra [VE]

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.

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.

tenofovir disoproxil fumarate 300 mg + emtricitabine 200 mg tablet, 30

9564J

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

Authority required (STREAMLINED)

4470
HIV infection

Treatment Phase: Continuing

Clinical criteria:
Patient must have previously received PBS-subsidised therapy for HIV infection.

tenofovir disoproxil fumarate 300 mg + emtricitabine 200 mg + efavirenz 600 mg tablet, 30

9565K

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

Authority required (STREAMLINED)
4470
HIV infection

Treatment Phase: Continuing
Clinical criteria:
Patient must have previously received PBS-subsidised therapy for HIV infection.

tenofvir disoproxil fumarate 300 mg + emtricitabine 200 mg + elvitegravir 150 mg + cobicistat 150 mg tablet, 30

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Other antivirals

- **Dolutegravir**
  Authority required (STREAMLINED)
  4512
  HIV infection
  Treatment Phase: Initial
  Clinical criteria:
  Patient must be antiretroviral treatment naive, AND
  The treatment must be in combination with other antiretroviral agents.

  Authority required (STREAMLINED)
  4454
  HIV infection
  Treatment Phase: Continuing
  Clinical criteria:
  Patient must have previously received PBS-subsidised therapy for HIV infection, AND
  The treatment must be in combination with other antiretroviral agents.

dolutegravir 50 mg tablet, 30

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- **Enfuvirtide**
  Authority required (STREAMLINED)
  3597
  Treatment of HIV infection, in addition to optimised background therapy in combination with other antiretroviral agents in an antiretroviral experienced patient who, after each of at least three different antiretroviral regimens that have included one drug from at least 3 different antiretroviral classes, has experienced virological failure or clinical failure or genotypic resistance.
  Virological failure is defined as a viral load greater than 400 copies per mL on two consecutive occasions, while clinical failure is linked to emerging signs and symptoms of progressing HIV infection or treatment-limiting toxicity

  enfuvirtide 90 mg injection [60 x 90 mg vials] (&) inert substance diluent [60 x 1.1 mL vials], 1 pack

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- **Maraviroc**
  Authority required (STREAMLINED)
  3599
  Treatment, in addition to optimised background therapy in combination with other antiretroviral agents, of an antiretroviral experienced patient infected with only CCR5-tropic HIV-1, who, after each of at least three different antiretroviral regimens that have included one drug from at least 3 different antiretroviral classes, has experienced virological failure or clinical failure or genotypic resistance. A tropism assay to determine CCR5 only strain status is required prior to initiation. Individuals with CXCR4 tropism demonstrated at any time point are not eligible.
  Virological failure is defined as a viral load greater than 400 copies per mL on two consecutive occasions, while clinical failure is linked to emerging signs and symptoms of progressing HIV infection or treatment-limiting toxicity

  maraviroc 150 mg tablet, 60

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  maraviroc 300 mg tablet, 60

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</table>
RALTEGRAVIR

**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:** Initial

**Clinical criteria:**

Patient must have previously received PBS-subsidised therapy for HIV infection, **AND**

The treatment must be in combination with other antiretroviral agents.

**Raltegravir 400 mg tablet, 60**

9523F

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RALTEGRAVIR

**Authority required (STREAMLINED)**

**4275**

HIV infection

**Treatment Phase:** Initial

**Clinical criteria:**

The treatment must be in combination with other antiretroviral agents, **AND**

Patient must be antiretroviral experienced with at least 6 months therapy with 2 alternate classes of anti-retroviral therapy, **AND**

Patient must have a CD4 count of less than 500 per cubic millimetre; **OR**

Patient must have symptomatic HIV disease.

**Population criteria:**

Patient must be aged 2 years or older.

**Authority required (STREAMLINED)**

**4274**

HIV infection

**Treatment Phase:** Continuing

**Clinical criteria:**

The treatment must be in combination with other antiretroviral agents, **AND**

Patient must be antiretroviral experienced with at least 6 months therapy with 2 alternate classes of anti-retroviral therapy, **AND**

Patient must have previously received PBS-subsidised therapy for HIV infection.

**Population criteria:**

Patient must be aged 2 years or older.

**Raltegravir 100 mg tablet: chewable, 60**

2760G

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**Raltegravir 25 mg tablet: chewable, 60**

2736B

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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.

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**azacitidine 100 mg injection, 1 x 100 mg vial**

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**AZACITIDINE**

**Authority required**

Continuing 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% blasts and multi-lineage dysplasia, according to World Health Organisation (WHO) Classification;

who has previously been issued with an authority prescription for azacitidine and does not have progressive disease.

Authority applications for continuing treatment may be made by telephone on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Up to six cycles will be authorised.

**Note**

Any queries concerning the arrangements to prescribe azacitidine may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.
Written applications for authority to prescribe azacitidine should be forwarded to:
Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001
Special Pricing Arrangements apply.

azacitidine 100 mg injection, 1 x 100 mg vial
9598E

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**CYTOTOXIC ANTIBIOTICS AND RELATED SUBSTANCES**

**Anthracyclines and related substances**

- **DOXORUBICIN HYDROCHLORIDE-PEGYLATED LIPOSOMAL**
  - **Authority required (STREAMLINED)**
  - 3348
    - Treatment of AIDS-related Kaposi's sarcoma in patients with CD4 cell counts of less than 200 per cubic millimetre and extensive mucocutaneous involvement
  - **Authority required (STREAMLINED)**
  - 3349
    - Treatment of AIDS-related Kaposi's sarcoma in patients with CD4 cell counts of less than 200 per cubic millimetre and extensive visceral involvement

- **doxorubicin hydrochloride-pegylated liposomal 20 mg/10 mL injection, 1 x 10 mL vial**
  - **Brand Name and Manufacturer**
  - 5705G

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**IMMUNOSTIMULANTS**

**IMMUNOSTIMULANTS**

* Colony stimulating factors

- **FILGRASTIM**
  - **Authority required (STREAMLINED)**
  - 3357
    - For use in a patient undergoing induction and consolidation therapy for acute myeloid leukaemia
  - **Authority required (STREAMLINED)**
  - 3358
    - Mobilisation of peripheral blood progenitor cells to facilitate harvest of such cells for autologous transplantation into a patient with a non-myeloid malignancy who has had myeloablative or myelosuppressive therapy
  - **Authority required (STREAMLINED)**
  - 3359
    - Mobilisation of peripheral blood progenitor cells, in a normal volunteer, for use in allogeneic transplantation
  - **Authority required (STREAMLINED)**
  - 3360
    - A patient receiving marrow-ablative chemotherapy and subsequent bone marrow transplantation
  - **Authority required (STREAMLINED)**
  - 3361
    - A patient with a non-myeloid malignancy receiving marrow-ablative chemotherapy and subsequent autologous peripheral blood progenitor cell transplantation
  - **Authority required (STREAMLINED)**
  - 3362
    - A patient with chronic cyclic neutropenia (absolute neutrophil count of less than 500 million cells per litre lasting for 3 days per cycle, measured over 3 separate cycles, and, either having experienced a life-threatening infectious episode requiring hospitalisation and treatment with intravenous antibiotics, or having recurrent clinically significant infections (a minimum of 3 in the previous 12 months))
  - **Authority required (STREAMLINED)**
  - 3363
    - A patient with inoperable Stage III, IVa or IVb squamous cell carcinoma of the oral cavity, larynx, oropharynx or hypopharynx receiving neoadjuvant treatment with docetaxel in combination with cisplatin and fluorouracil who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned
  - **Authority required (STREAMLINED)**
  - 3364
    - 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
A patient with breast cancer receiving standard dose adjuvant chemotherapy who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned

**Authority required (STREAMLINED)**

**3363**

A patient receiving chemotherapy for B-cell chronic lymphocytic leukaemia with fludarabine and cyclophosphamide who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned

**Authority required (STREAMLINED)**

**3364**

A patient receiving first-line chemotherapy for Hodgkin disease who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned

**Authority required (STREAMLINED)**

**3365**

A patient receiving chemotherapy for myeloma who has had a prior episode of febrile neutropenia, and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned

**Authority required (STREAMLINED)**

**3366**

A patient with severe congenital neutropenia (absolute neutrophil count of less than 100 million cells per litre measured on 3 occasions, with readings at least 2 weeks apart, and in whom a bone marrow examination has shown evidence of maturational arrest of the neutrophil lineage)

**Authority required (STREAMLINED)**

**3367**

A patient with severe chronic neutropenia (absolute neutrophil count of less than 1,000 million cells per litre measured on 3 occasions, with readings at least 2 weeks apart, or evidence of neutrophil dysfunction, and, either having experienced a life-threatening infectious episode requiring hospitalisation and treatment with intravenous antibiotics in the previous 12 months, or having recurrent clinically significant infections (a minimum of 3 in the previous 12 months))

**Authority required (STREAMLINED)**

**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)**

**3384**

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)
### Antineoplastic and Immunomodulating Agents

**Filgrastim 120 microgram/0.2 mL injection, 10 x 0.2 mL syringes**

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**Filgrastim 300 microgram/0.5 mL injection, 10 x 0.5 mL syringes**

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**Filgrastim 300 microgram/0.5 mL injection, 5 x 0.5 mL syringes**

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**Filgrastim 480 microgram/0.5 mL injection, 10 x 0.5 mL syringes**

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**Filgrastim 480 microgram/0.5 mL injection, 5 x 0.5 mL syringes**

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**Filgrastim 480 microgram/1.6 mL injection, 10 x 1.6 mL vials**

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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 leukaemia

Authority required (STREAMLINED)
3398
Patients being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in Ewing's sarcoma

Authority required (STREAMLINED)
3399
Patients being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in germ cell tumours

Authority required (STREAMLINED)
3400
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 (STREAMLINED)
3401
Patients being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in neuroblastoma

Authority required (STREAMLINED)
3402
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 (STREAMLINED)
3403
Patients being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in osteosarcoma

Authority required (STREAMLINED)
3404
Patients being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in relapsed Hodgkin's disease

Authority required (STREAMLINED)
3405
Patients being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in rhabdomyosarcoma

LENOROGASTIM Powder for injection 13,400,000 i.u. (105 micrograms) vial, 10

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LENOROGASTIM Powder for injection 33,600,000 i.u. (263 micrograms) vial, 10

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### PEGIFILGRASTIM

Authority required (STREAMLINED)
3357
For use in a patient undergoing induction and consolidation therapy for acute myeloid leukaemia

Authority required (STREAMLINED)
3362
A patient with breast cancer receiving standard dose adjuvant chemotherapy who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned

Authority required (STREAMLINED)
3363
A patient receiving chemotherapy for B-cell chronic lymphocytic leukaemia with fludarabine and cyclophosphamide who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned

Authority required (STREAMLINED)
3364
A patient receiving first-line chemotherapy for Hodgkin disease who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned

**Authority required (STREAMLINED)**

**3365**

A patient receiving chemotherapy for myeloma who has had a prior episode of febrile neutropenia, and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned

**Authority required (STREAMLINED)**

**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 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 breast cancer (adjuvant chemotherapy with docetaxel in combination with an anthracycline and cyclophosphamide)

**Authority required (STREAMLINED)**

**3371**

A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in germ cell tumours

**Authority required (STREAMLINED)**

**3372**

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)**

**3373**

A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in neuroblastoma

**Authority required (STREAMLINED)**

**3374**

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)**

**3375**

A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in relapsed Hodgkin disease

**Authority required (STREAMLINED)**

**3376**

A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in sarcoma

**Authority required (STREAMLINED)**

**3377**

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)

**pegfilgrastim 6 mg/0.6 mL injection, 1 x 0.6 mL syringe**

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**Interferons**

- **INTERFERON ALFA-2A**

**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.

**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

**interferon alfa-2a 3 million international units/0.5 mL injection, 1 x 0.5 mL syringe**

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**interferon alfa-2a 4.5 million international units/0.5 mL injection, 1 x 0.5 mL syringe**

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**interferon alfa-2a 6 million international units/0.5 mL injection, 1 x 0.5 mL syringe**

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**interferon alfa-2a 9 million international units/0.5 mL injection, 1 x 0.5 mL syringe**

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**INTERFERON ALFA-2B**

**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.

**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

**interferon alfa-2b 10 million international units/mL injection, 5 x 1 mL vials**

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**interferon alfa-2b 18 million international units/1.2 mL injection, 1 x 1.2 mL cartridge**

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**interferon alfa-2b 18 million international units/3 mL injection, 1 x 3 mL vial**

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interferon alfa-2b 25 million international units/2.5 mL injection, 1 x 2.5 mL vial

5767M

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interferon alfa-2b 30 million international units/1.2 mL injection, 1 x 1.2 mL cartridge

5764J

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interferon alfa-2b 60 million international units/1.2 mL injection, 1 x 1.2 mL cartridge

5765K

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**INTERFERON GAMMA-1B**

**Authority required (STREAMLINED)**

**3385**

Treatment of chronic granulomatous disease in patients with frequent and severe infections despite adequate prophylaxis with antimicrobial agents

interferon gamma-1b 2 million international units (100 microgram/0.5 mL) injection, 6 x 0.5 mL vials

5769P

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**PEGINTERFERON ALFA-2A**

**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.

**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

**Authority required (STREAMLINED)**

**3978**

Treatment, as sole PBS-subsidised therapy, in a patient with chronic hepatitis B with cirrhosis who has detectable HBV DNA. Persons with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy.

Treatment is limited to 1 course of treatment for a duration of up to 48 weeks

**Authority required (STREAMLINED)**

**3412**

Treatment, managed by an accredited treatment centre, of chronic hepatitis C in patients 18 years or older who have compensated liver disease and who have received no prior interferon alfa or peginterferon alfa treatment for hepatitis C and have a contraindication to ribavirin, who satisfy all of the following criteria:

1. Documented chronic hepatitis C infection (repeatedly anti-HCV positive and HCV RNA positive);
2. Female patients of child-bearing age are not pregnant, not breast-feeding, and are using an effective form of contraception.

The treatment course is limited to up to 48 weeks.

Patients may only continue treatment after the first 12 weeks if the result of an HCV RNA quantitative assay (performed at the same laboratory using the same test) shows that the plasma HCV RNA has become undetectable or the viral load has decreased by at least a 2 log drop

**Note**

Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:

1. a nurse educator/counsellor for patients; and
2. 24 hour access by patients to medical advice; and
3. an established liver clinic; and
4. facilities for safe liver biopsy.
PEGINTERFERON ALFA-2A (&) RIBAVIRIN

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.

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.

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 prior treatment with interferon alfa or peginterferon alfa for hepatitis C if using peginterferon and ribavirin without an NS3 protease inhibitor, or, in triple combination therapy with boceprevir; OR
Patient must have received prior treatment with interferon alfa or peginterferon alfa for hepatitis C if using peginterferon and ribavirin in triple combination therapy with telaprevir; OR
Patient must have received prior treatment with interferon alfa or peginterferon alfa for hepatitis C if using peginterferon and ribavirin in triple combination therapy with simprevir; AND

The treatment must be limited to a maximum duration of 24 weeks in patients using peginterferon and ribavirin in triple combination therapy with telaprevir who were prior treatment relapsers and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at week 8, and for whom the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is detectable but less than or equal to 1000 IU/mL; or (iii) have hepatic cirrhosis; OR

The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin in triple combination therapy with simprevir who: (i) were prior treatment partial or null responders; or (ii) were prior treatment relapsers and for whom the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is detectable but less than or equal to 1000 IU/mL; or (iii) have hepatic cirrhosis; OR

The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin 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 and in whom plasma HCV RNA is detectable by an HCV RNA qualitative assay at week 4, and undetectable by an HCV RNA quantitative assay at week 8, 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

The treatment must be limited to a maximum duration of 24 weeks in patients using peginterferon and ribavirin in triple combination therapy with simprevir if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is detectable but less than 25 IU/mL, AND

The treatment must cease in patients using peginterferon and ribavirin 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 simeprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12, AND

The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24, AND

The treatment must cease in patients using peginterferon and ribavirin in combination with simprevir if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is greater than or equal to 25 IU/mL, AND

The treatment must cease in patients using peginterferon and ribavirin in combination with simprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12, AND

The treatment must cease in patients using peginterferon and ribavirin in combination with simprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24.
**Population criteria:**
Patient must be aged 18 years or older, **AND**
Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

**Treatment criteria:**
Must be treated in an accredited treatment centre.
Evidence of chronic genotype 1 hepatitis C infection (repeatedly anti-HCV positive and HCV RNA positive) must be documented in the patient’s medical records.

**Authority required (STREAMLINED)**
4197
Chronic genotype 1 hepatitis C infection

**Clinical criteria:**
Patient must have compensated liver disease, **AND**
Patient must not have received prior interferon alfa or peginterferon alfa treatment for hepatitis C, **AND**
The treatment must be limited to a maximum duration of 24 weeks in patients using peginterferon and ribavirin in triple combination therapy with telaprevir and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at weeks 4 and 12; **OR**
The treatment must be limited to a maximum duration of 28 weeks in patients using peginterferon and ribavirin in triple combination therapy with boceprevir and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at weeks 8 and 24; **OR**
The treatment must be limited to a maximum duration of 24 weeks in patients using peginterferon and ribavirin in triple combination therapy with simeprevir and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at week 4; **OR**
The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin without an NS3 protease inhibitor; **OR**
The treatment must be limited to a maximum duration of 48 weeks in patients: (i) using peginterferon and ribavirin in triple combination therapy with boceprevir and in whom plasma HCV RNA is detectable by an HCV RNA qualitative assay at week 8, and undetectable by an HCV RNA qualitative assay at week 24; or (ii) using peginterferon and ribavirin in triple combination therapy with boceprevir who have hepatic cirrhosis; **OR**
The treatment must be limited to a maximum duration of 48 weeks in patients: (i) using peginterferon and ribavirin in triple combination therapy with telaprevir and for whom the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is detectable but less than or equal to 1000 IU/mL; or (ii) using peginterferon and ribavirin in triple combination therapy with telaprevir who have hepatic cirrhosis; **OR**
The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin in triple combination therapy with simeprevir and for whom the results of an HCV RNA qualitative assay at week 4 show that the plasma HCV RNA is detectable but less than 25 IU/mL, **AND**
The treatment must cease in patients using peginterferon and ribavirin without an NS3 protease inhibitor unless the results of an HCV RNA quantitative assay at week 12 (performed at the same laboratory using the same test) show that plasma HCV RNA has become undetectable or the viral load has decreased by at least a 2 log drop, **AND**
The treatment must cease in patients using peginterferon and ribavirin in combination with boceprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24, **AND**
The treatment must cease in patients using peginterferon and ribavirin in combination with 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 quantitative assay at week 4 show that the plasma HCV RNA is greater than 25 IU/mL, **AND**
The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24, **AND**
The treatment must cease in patients using peginterferon and ribavirin in combination with simeprevir if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is greater than or equal to 25 IU/mL, **AND**
The treatment must cease in patients using peginterferon and ribavirin in combination with simeprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12, **AND**
The treatment must cease in patients using peginterferon and ribavirin in combination with simeprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24.

**Population criteria:**
Patient must be aged 18 years or older, **AND**
Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

**Treatment criteria:**
Must be treated in an accredited treatment centre.
Evidence of chronic hepatitis C infection (repeatedly anti-HCV positive and HCV RNA positive) must be documented in the patient’s medical records.

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

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.

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.

| peginterferon alfa-2a 135 microgram/0.5 mL injection [4 x 0.5 mL syringes] (&) ribavirin 200 mg tablet [168 tablets], 1 pack |
|---|---|---|---|
| 9524G | Max Qty Packs | No. of Rpts | Premium $ | DPMQ $ |
| 2 | 5 | .. | *3072.84 | |
| Brand Name and Manufacturer | Pegasys RBV [RO] |

| peginterferon alfa-2a 180 microgram/0.5 mL injection [4 x 0.5 mL syringes] (&) ribavirin 200 mg tablet [112 tablets], 1 pack |
|---|---|---|---|
| 9525H | Max Qty Packs | No. of Rpts | Premium $ | DPMQ $ |
| 2 | 5 | .. | *3085.28 | |
| Brand Name and Manufacturer | Pegasys RBV [RO] |
**PEGINTERFERON ALFA-2B (& RIBAVIRIN)**

**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.

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.

**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 NS3 protease inhibitor, **OR**
- Patient must have received prior treatment with interferon alfa or peginterferon alfa for hepatitis C if using peginterferon and ribavirin in triple combination therapy with telaprevir; **OR**
- Patient must have received prior treatment with interferon alfa or peginterferon alfa for hepatitis C if using peginterferon and ribavirin in triple combination therapy with 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 simeprevir, **AND**
- The treatment must be limited to a maximum duration of 24 weeks in patients using peginterferon and ribavirin in triple combination therapy with telaprevir who were prior treatment relapsers and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at weeks 4 and 12; **OR**
- The treatment must be limited to a maximum duration of 36 weeks in patients using peginterferon and ribavirin in triple combination therapy with boceprevir who were prior treatment partial responders or relapsers and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at weeks 8 and 12; **OR**
- The treatment must be limited to a maximum duration of 24 weeks in patients using peginterferon and ribavirin in triple combination therapy with simeprevir who were prior treatment relapsers and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at week 4; **OR**
- The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin without an NS3 protease inhibitor; **OR**
- The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin in triple combination therapy with boceprevir who: (i) were prior treatment null responders; or (ii) were prior treatment partial responders or relapsers and in whom plasma HCV RNA is detectable by an HCV RNA qualitative assay at week 8, and undetectable by an HCV RNA qualitative assay at week 12; **AND**
- The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin in triple combination therapy with telaprevir who: (i) were prior treatment partial or null responders; or (ii) were prior treatment relapsers and for whom the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is detectable but less than or equal to 1000 IU/mL; or (iii) have hepatic cirrhosis; **OR**
- The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin in triple combination therapy with simeprevir who: (i) were prior treatment partial or null responders; or (ii) were prior treatment relapsers and for whom the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is detectable but less than or equal to 1000 IU/mL, **AND**
- The treatment must be limited to a maximum duration of 24 weeks in patients using peginterferon and ribavirin in triple combination therapy with boceprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24; **AND**
- The treatment must be limited to a maximum duration of 24 weeks in patients using peginterferon and ribavirin in combination with telaprevir if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is greater than or equal to 25 IU/mL, **AND**
- The treatment must be limited to a maximum duration of 24 weeks in patients using peginterferon and ribavirin in combination with simeprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12; **AND**
- The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12.

**Patient must have received 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 in triple combination therapy with telaprevir; OR**

**Patient must have received prior treatment with interferon alfa or peginterferon alfa for hepatitis C if using peginterferon and ribavirin in triple combination therapy with 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 simeprevir, AND**

**The treatment must be limited to a maximum duration of 24 weeks in patients using peginterferon and ribavirin in triple combination therapy with telaprevir who were prior treatment relapsers and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at weeks 4 and 12; OR**

**The treatment must be limited to a maximum duration of 36 weeks in patients using peginterferon and ribavirin in triple combination therapy with boceprevir who were prior treatment partial responders or relapsers and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at weeks 8 and 12; OR**

**The treatment must be limited to a maximum duration of 24 weeks in patients using peginterferon and ribavirin in triple combination therapy with simeprevir who were prior treatment relapsers and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at week 4; OR**

**The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin without an NS3 protease inhibitor; OR**

**The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin in triple combination therapy with boceprevir who: (i) were prior treatment null responders; or (ii) were prior treatment partial responders or relapsers and in whom plasma HCV RNA is detectable by an HCV RNA qualitative assay at week 8, and undetectable by an HCV RNA qualitative assay at week 12; **AND**

**The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin in triple combination therapy with telaprevir who: (i) were prior treatment partial or null responders; or (ii) were prior treatment relapsers and for whom the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is detectable but less than or equal to 1000 IU/mL; or (iii) have hepatic cirrhosis; **OR**

**The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin in triple combination therapy with simeprevir who: (i) were prior treatment partial or null responders; or (ii) were prior treatment relapsers and for whom the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is detectable but less than 25 IU/mL, **AND**

**The treatment must cease in patients using peginterferon and ribavirin without an NS3 protease inhibitor if HCV RNA is detectable by an HCV RNA qualitative assay at week 12, **AND**

**The treatment must cease in patients using peginterferon and ribavirin in combination with boceprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12, **AND**

**The treatment must cease in patients using peginterferon and ribavirin in combination with boceprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24, **AND**

**The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is greater than 1000 IU/mL, **AND**

**The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is greater than or equal to 25 IU/mL, **AND**

**The treatment must cease in patients using peginterferon and ribavirin in combination with simeprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12, **AND**
The treatment must cease in patients using peginterferon and ribavirin in combination with simeprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24.

Population criteria:
Patient must be aged 18 years or older, AND
Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

Treatment criteria:
Must be treated in an accredited treatment centre.

Evidence of chronic genotype 1 hepatitis C infection (repeatedly anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.

Authority required (STREAMLINED)

Clinical criteria:
Patient must have compensated liver disease, AND
Patient must not have received prior interferon alfa or peginterferon alfa treatment for hepatitis C, AND
The treatment must be limited to a maximum duration of 24 weeks in patients using peginterferon and ribavirin in triple combination therapy with telaprevir and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at weeks 4 and 12; OR
The treatment must be limited to a maximum duration of 28 weeks in patients using peginterferon and ribavirin in triple combination therapy with boceprevir and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at weeks 8 and 24; OR
The treatment must be limited to a maximum duration of 24 weeks in patients using peginterferon and ribavirin in triple combination therapy with simeprevir and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at week 4; OR
The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin without an NS3 protease inhibitor; OR
The treatment must be limited to a maximum duration of 48 weeks in patients: (i) using peginterferon and ribavirin in triple combination therapy with boceprevir and in whom plasma HCV RNA is detectable by an HCV RNA qualitative assay at week 8, and undetectable by an HCV RNA qualitative assay at week 24; or (ii) using peginterferon and ribavirin in triple combination therapy with boceprevir who have hepatic cirrhosis; OR
The treatment must be limited to a maximum duration of 48 weeks in patients: (i) using peginterferon and ribavirin in triple combination therapy with telaprevir and for whom the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is detectable but less than or equal to 1000 IU/mL; or (ii) using peginterferon and ribavirin in triple combination therapy with telaprevir who have hepatic cirrhosis; OR
The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin in triple combination therapy with simeprevir and for whom the results of an HCV RNA qualitative assay at week 4 show that the plasma HCV RNA is detectable but less than 25 IU/mL, AND
The treatment must cease in patients using peginterferon and ribavirin without an NS3 protease inhibitor unless the results of an HCV RNA quantitative assay at week 12 (performed at the same laboratory using the same test) show that plasma HCV RNA has become undetectable or the viral load has decreased by at least a 2 log drop, AND
The treatment must cease in patients using peginterferon and ribavirin in combination with boceprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24, AND
The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is greater than 1000 IU/mL, AND
The treatment must cease in patients using peginterferon and ribavirin in combination with simeprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12, AND
The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24, AND
The treatment must cease in patients using peginterferon and ribavirin in combination with simeprevir if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is greater than or equal to 25 IU/mL, AND
The treatment must cease in patients using peginterferon and ribavirin in combination with simeprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12, AND
The treatment must cease in patients using peginterferon and ribavirin in combination with simeprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24.

Population criteria:
Patient must be aged 18 years or older, AND
Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

Treatment criteria:
Must be treated in an accredited treatment centre.

Evidence of chronic hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.

For patients using peginterferon and ribavirin without an NS3 protease inhibitor who are viral negative at week 12, an HCV RNA qualitative assay at week 24 is unnecessary.

Authority required (STREAMLINED)

Clinical criteria:
Patient must have compensated liver disease, AND
Patient must not have received prior interferon alfa or peginterferon alfa treatment for hepatitis C, AND
The treatment must be limited to a maximum duration of 24 weeks in patients using peginterferon and ribavirin in triple combination therapy with telaprevir and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at weeks 4 and 12; OR
The treatment must be limited to a maximum duration of 28 weeks in patients using peginterferon and ribavirin in triple combination therapy with boceprevir and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at weeks 8 and 24; OR
The treatment must be limited to a maximum duration of 24 weeks in patients using peginterferon and ribavirin in triple combination therapy with simeprevir and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at week 4; OR
The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin without an NS3 protease inhibitor; OR
The treatment must be limited to a maximum duration of 48 weeks in patients: (i) using peginterferon and ribavirin in triple combination therapy with boceprevir and in whom plasma HCV RNA is detectable by an HCV RNA qualitative assay at week 8, and undetectable by an HCV RNA qualitative assay at week 24; or (ii) using peginterferon and ribavirin in triple combination therapy with boceprevir who have hepatic cirrhosis; OR
The treatment must be limited to a maximum duration of 48 weeks in patients: (i) using peginterferon and ribavirin in triple combination therapy with telaprevir and for whom the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is detectable but less than or equal to 1000 IU/mL; or (ii) using peginterferon and ribavirin in triple combination therapy with telaprevir who have hepatic cirrhosis; OR
The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin in triple combination therapy with simeprevir and for whom the results of an HCV RNA qualitative assay at week 4 show that the plasma HCV RNA is detectable but less than 25 IU/mL, AND
The treatment must cease in patients using peginterferon and ribavirin without an NS3 protease inhibitor unless the results of an HCV RNA quantitative assay at week 12 (performed at the same laboratory using the same test) show that plasma HCV RNA has become undetectable or the viral load has decreased by at least a 2 log drop, AND
The treatment must cease in patients using peginterferon and ribavirin in combination with boceprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24, AND
The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is greater than 1000 IU/mL, AND
The treatment must cease in patients using peginterferon and ribavirin in combination with simeprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12, AND
The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24, AND
The treatment must cease in patients using peginterferon and ribavirin in combination with simeprevir if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is greater than or equal to 25 IU/mL, AND
The treatment must cease in patients using peginterferon and ribavirin in combination with simeprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12, AND
The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24.
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.
No increase in the maximum number of repeats may be authorised.

**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 quantitative 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.

**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**

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PEGINTERFERON ALFA-2B (&) RIBAVIRIN

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.

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.

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.

Authority required (STREAMLINED)

4198
Chronic genotype 1 hepatitis C infection

Clinical criteria:
The treatment must be the sole PBS-subsidised treatment for hepatitis C, AND
Patient must have compensated liver disease, AND
Patient must not have received prior interferon alfa or peginterferon alfa treatment for hepatitis C, AND
The treatment must be limited to a maximum duration of 48 weeks, AND
The treatment must cease unless the results of an HCV RNA quantitative assay at week 12 (performed at the same laboratory using the same test) show that plasma HCV RNA has become undetectable or the viral load has decreased by at least a 2 log drop.

Population criteria:
Patient must weigh at least 27 kg, AND
Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

Treatment criteria:
Must be treated in an accredited treatment centre.
Evidence of chronic hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.
For patients who are viral negative at week 12, an HCV RNA qualitative assay at week 24 is unnecessary.

Authority required (STREAMLINED)
Chronic non-genotype 1 hepatitis C infection

Clinical criteria:
The treatment must be the sole PBS-subsidised treatment for hepatitis C, AND
Patient must have compensated liver disease, AND
The condition must be genotype 2, 3, 4, 5 or 6 hepatitis C, AND
Patient must have failed prior treatment with interferon based therapies (non-pegylated or pegylated), AND
Patient must have received no more than one prior treatment with interferon alfa or peginterferon alfa for hepatitis C, AND
The treatment must be limited to a maximum duration of 48 weeks, AND
The treatment must cease if HCV RNA is detectable by an HCV RNA qualitative assay at week 12.

Population criteria:
Patient must weigh at least 27 kg, AND
Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

Treatment criteria:
Must be treated in an accredited treatment centre.
Evidence of chronic hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.

Authority required (STREAMLINED)

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.

Authority required (STREAMLINED)

Chronic genotype 1 hepatitis C infection

Clinical criteria:
Patient must have compensated liver disease, AND
Patient must have failed prior treatment with interferon based therapies (non-pegylated or pegylated), AND
Patient must have received no more than one prior treatment with interferon alfa or peginterferon alfa for hepatitis C if using peginterferon and ribavirin without an NS3 protease inhibitor, or, in triple combination therapy with boceprevir; OR
Patient must have received prior treatment with interferon alfa or peginterferon alfa for hepatitis C if using peginterferon and ribavirin in triple combination therapy with telaprevir; OR
Patient must have received prior treatment with interferon alfa or peginterferon alfa for hepatitis C if using peginterferon and ribavirin in triple combination therapy with simeprevir, 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 in triple combination therapy with telaprevir who were prior treatment partial responders or relapers and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at week 4; OR The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin without an NS3 protease inhibitor; OR The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin in triple combination therapy with boceprevir who: (i) were prior treatment null responders; or (ii) were prior treatment partial responders or relapers and in whom plasma HCV RNA is detectable by an HCV RNA qualitative assay at week 8, and undetectable by an HCV RNA qualitative assay at week 12; or (iii) have hepatic cirrhosis; OR The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin in triple combination therapy with telaprevir who: (i) were prior treatment partial or null responders; or (ii) were prior treatment relapers and for whom the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is detectable but less than or equal to 1000 IU/mL; or (iii) have hepatic cirrhosis; OR The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin in triple combination therapy with 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 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 simeprevir who: (i) were prior treatment partial or null responders; or (ii) were prior treatment relapers and for whom the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is detectable but less than 25 IU/mL, AND The treatment must cease in patients using peginterferon and ribavirin without an NS3 protease inhibitor if HCV RNA is detectable by an HCV RNA qualitative assay at week 12, AND The treatment must cease in patients using peginterferon and ribavirin in combination with boceprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12, AND The treatment must cease in patients using peginterferon and ribavirin in combination with boceprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24, AND The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is greater than 1000 IU/mL, AND The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12, AND The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24, AND The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24, AND The treatment must cease in patients using peginterferon and ribavirin in combination with simeprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12, AND The treatment must cease in patients using peginterferon and ribavirin in combination with simeprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24, AND The treatment must cease in patients using peginterferon and ribavirin in combination with simeprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24, AND The treatment must cease in patients using peginterferon and ribavirin in combination with simeprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24, AND The treatment must cease in patients using peginterferon and ribavirin in combination with simeprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24, AND The treatment must cease in patients using peginterferon and ribavirin in combination with simeprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24, AND The treatment must cease in patients using peginterferon and ribavirin in combination with simeprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24, AND The treatment must cease in patients using peginterferon and ribavirin in combination with simeprevir if HCV RNA is detectable by an HCV RNA quantitative assay at week 4, 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

**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.

**Authority required (STREAMLINED)**

4197 Chronic genotype 1 hepatitis C infection

**Clinical criteria:**

Patient must have compensated liver disease, AND Patient must not have received prior interferon alfa or peginterferon alfa treatment for hepatitis C, AND The treatment must be limited to a maximum duration of 24 weeks in patients using peginterferon and ribavirin in triple combination therapy with telaprevir and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at weeks 4 and 12; OR The treatment must be limited to a maximum duration of 28 weeks in patients using peginterferon and ribavirin in triple combination therapy with boceprevir and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at weeks 8 and 24; OR The treatment must be limited to a maximum duration of 24 weeks in patients using peginterferon and ribavirin in triple combination therapy with simeprevir and in whom plasma HCV RNA is undetectable by an HCV RNA quantitative assay at week 4; OR The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin 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 25 IU/mL, AND The treatment must cease in patients using peginterferon and ribavirin without an NS3 protease inhibitor if HCV RNA is detectable by an HCV RNA qualitative assay at week 12, AND The treatment must cease in patients using peginterferon and ribavirin in combination with boceprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12, AND The treatment must cease in patients using peginterferon and ribavirin in combination with boceprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24, AND The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is greater than 1000 IU/mL, AND The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12, AND The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24, AND The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA quantitative assay at week 4, OR The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin without an NS3 protease inhibitor; OR The treatment must be limited to a maximum duration of 48 weeks in patients: (i) using peginterferon and ribavirin in triple combination therapy with boceprevir and in whom plasma HCV RNA is detectable by an HCV RNA qualitative assay at week 8, and undetectable by an HCV RNA qualitative assay at week 24; or (ii) using peginterferon and ribavirin in triple combination therapy with boceprevir who have hepatic cirrhosis; OR The treatment must be limited to a maximum duration of 48 weeks in patients: (i) using peginterferon and ribavirin in triple combination therapy with telaprevir and for whom the results of an HCV RNA quantitative assay at week 4 show that the
plasma HCV RNA is detectable but less than or equal to 1000 IU/mL; or (ii) using peginterferon and ribavirin in triple combination therapy with telaprevir who have hepatic cirrhosis; OR
The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin in triple combination therapy with simeprevir and for whom the results of an HCV RNA qualitative assay at week 4 show that the plasma HCV RNA is detectable but less than 25 IU/mL, AND
The treatment must cease in patients using peginterferon and ribavirin without an NS3 protease inhibitor unless the results of an HCV RNA quantitative assay at week 12 (performed at the same laboratory using the same test) show that plasma HCV RNA has become undetectable or the viral load has decreased by at least a 2 log drop, AND
The treatment must cease in patients using peginterferon and ribavirin in combination with boceprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24, AND
The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is greater than 1000 IU/mL, AND
The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12, AND
The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is greater than 25 IU/mL, AND
The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12, AND
The treatment must cease in patients using peginterferon and ribavirin in combination with simeprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24.

Population criteria:
Patient must be aged 18 years or older, AND
Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

Treatment criteria:
Must be treated in an accredited treatment centre.
Evidence of chronic hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.
For patients using peginterferon and ribavirin without an NS3 protease inhibitor who are viral negative at week 12, an HCV RNA qualitative assay at week 24 is unnecessary.

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

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.

**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>Peginterferon alpha-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</th>
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<td>9534T</td>
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<td>Max Qty Packs</td>
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<tr>
<th>Peginterferon alpha-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</th>
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<td>Max Qty Packs</td>
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<tr>
<th>Peginterferon alpha-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</th>
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**Other immunostimulants**

- **PLERIXAFOR**
  - **Authority required (STREAMLINED)**
  - **4549**
  - Mobilisation of haematopoietic stem cells

  **Clinical criteria:**
  - The treatment must be in combination with granulocyte-colony stimulating factor (G-CSF), **AND**
  - Patient must have lymphoma; OR
  - Patient must have multiple myeloma, **AND**
  - Patient must require autologous stem cell transplantation, **AND**
  - Patient must have failed previous stem cell collection; OR
  - Patient must be undergoing chemotherapy plus G-CSF mobilisation and their peripheral blood CD34+ count is less than 10,000 per millilitre or less than 10 million per litre on the day of planned collection; OR
  - Patient must be undergoing chemotherapy plus G-CSF mobilisation and the first apheresis has yielded less than 1 million CD34+ cells/kg.

  Evidence that the patient meets the PBS restriction criteria must be recorded in the patient's medical records.

**Note**

Applications for increased maximum quantities will only be authorised for patients with body weight greater than 100 kg.

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<tr>
<th>Plerixafor 24 mg/1.2 mL injection: subcutaneous infusion, 1 x 1.2 mL vial</th>
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</table>
**IMMUNOSUPPRESSANTS**

**Selective immunosuppressants**

**ABATACEPT**

**Authority required**

Severe active rheumatoid arthritis  

**Clinical criteria:**

- Patient must have severe active rheumatoid arthritis, AND  
- Patient must have received no PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition in the previous 24 months, AND  
- Patient must not have failed previous PBS-subsidised treatment with this drug for this condition, and have not already failed, or ceased to respond to, PBS-subsidised bDMARD treatment for this condition 5 times, AND  
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR  
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR  
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above, must include at least 3 months continuous treatment with each of at least 2 DMARDs, with one or more of the following DMARDs being used in place of the DMARDs which are contraindicated or not tolerated: (i) azathioprine at a dose of at least 1 mg/kg per day; and/or (ii) cyclosporin at a dose of at least 2 mg/kg/day; and/or (iii) sodium aurothiomalate at a dose of 50 mg weekly, AND  
- Patient must not receive more than 16 weeks of treatment under this restriction, AND  

**Population criteria:**  

- Patient must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.  
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.  
- For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab or tocilizumab.  
- If methotrexate is contraindicated according to the TGA-approved Product Information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.  
- The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances.  
- The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.  
- If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance and dose for each DMARD must be provided in the authority application.  

**Supporting Information Form:**  

- (1) a completed authority prescription form; and  
- (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form; and  
- (3) a signed patient acknowledgement.  

**Treatment criteria:**

- Must be treated by a rheumatologist; OR  
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.  
- For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab or tocilizumab.  
- If methotrexate is contraindicated according to the TGA-approved Product Information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.  
- The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances.  
- The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.  
- If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance and dose for each DMARD must be provided in the authority application.  

**The authority application must be made in writing and must include:**

- (1) a completed authority prescription form; and  
- (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form; and  
- (3) a signed patient acknowledgement.  

**At the time of authority application, medical practitioners should request the appropriate number of vials to provide sufficient drug, based on the weight of the patient, for a single infusion. Up to a maximum of 4 repeats will be authorised.**  

Assessment of a patient’s response to an initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted no later than 1 month from the date of completion of this initial course of treatment.  

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.  

Applicants for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient’s most recent course of PBS-subsidised treatment, within the timeframes specified below.
Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

- an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either
  - (a) a total active joint count of at least 20 active (swollen and tender) joints; or
  - (b) at least 4 active joints from the following list of major joints:
    - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
    - (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).
- The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.
- If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Where the baseline joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP is provided with the initial application, the same marker will be used to determine response.

**Note**
The Department of Human Services website (www.humanservices.gov.au) has details of the toxicities, including severity, which will be accepted for the following purposes:
- (a) exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose;
- (b) substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial;
- (c) exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy.

**Special Pricing Arrangements apply.**

**Authority required**

Severe active rheumatoid arthritis

_Treatment Phase: Initial treatment - Initial 2 (change or re-commencement of treatment after break of less than 24 months)._

**Clinical criteria:**

Patient must have a documented history of severe active rheumatoid arthritis, **AND**

Patient must have received prior PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition and are eligible to receive further bDMARD therapy, **AND**

Patient must not receive more than 16 weeks of treatment under this restriction, **AND**

The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

**Population criteria:**

Patient must be aged 18 years or older.

**Treatment criteria:**

Must be treated by a rheumatologist; **OR**

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab or tocilizumab.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug, based on the weight of the patient, for a single infusion. Up to a maximum of 4 repeats will be authorised.

Applications for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to a treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.
A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD.

An adequate response to treatment is defined as:

- an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and/or

(b) either of the following:

- an active joint count of fewer than 10 active (swollen and tender) joints; or
- a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or
- 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**

**TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alpha antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab) and the T-cell co-stimulation modulator (abatacept).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alpha antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:

- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy;
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alpha antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or

(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or

(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or

(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab and tocilizumab, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab. A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For subsequent courses of PBS-subsidised (excluding rituximab) 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 submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

**Abatacept patients:**

Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient’s weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity
of 4 and up to 3 repeats, must be submitted with the initial application. Rituximab patients: A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment. Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients: A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy. Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent. A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept patients: Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to treatment 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 and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response. The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

**Authority required**

Severe active rheumatoid arthritis

**Treatment Phase:** Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months) or Initial 2 (change or recommencement of treatment after break of less than 24 months) – balance of supply.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Initial 1 (new patient or patient recommencing treatment after break of more than 24 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement of treatment after break of less than 24 months) restriction to complete 16 weeks treatment, **AND**
The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Treatment criteria:**
- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Note**
Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:
- Department of Human Services
- Prior Written Approval of Complex Drugs
- Reply Paid 9826
- GPO Box 9826

**HOBBT TAS 7001**

**Authority required**
Severe active rheumatoid arthritis

**Treatment Phase:** Continuing treatment.

**Clinical criteria:**
- Patient must have a documented history of severe active rheumatoid arthritis, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

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

**Treatment criteria:**
- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab or tocilizumab.

An adequate response to treatment is defined as:
- an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; **AND**
- either of the following:
  - (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
  - (b) a reduction in the number of the following active joints, from at least 4, by at least 50%:
    - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
    - (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:
- (1) a completed authority prescription form; and
- (2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners should request the appropriate number of vials to provide sufficient drug, based on the weight of the patient, for a single infusion. Up to a maximum of 5 repeats will be authorised.

All applications for continuing treatment with this drug must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

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

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

Applications for authority to prescribe should be forwarded to:
TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alpha antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab) and the T-cell co-stimulation modulator (abatacept).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alpha antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:

- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy;
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alpha antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

1. How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or

(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or

(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or

(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy. Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab and tocilizumab, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:
- Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient’s weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.
- Rituximab patients:
  - A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.
  - Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
- It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.
Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients:
A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept patients:
Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

In order to trial rituximab, an antibody must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD.

However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements. To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

**Authority required**

Severe active rheumatoid arthritis

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the 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
**abatacept 250 mg injection, 1 x 250 mg vial**

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- **ALEMTUZUMAB**
  
  Authority required (STREAMLINED)

  4829
  
  Multiple sclerosis
  
  Treatment Phase: Continuing
  
  Clinical criteria:
  
  Patient must have previously been issued with an authority prescription for this drug, AND
  
  Patient must not show continuing progression of disability while on treatment with this drug, AND
  
  Patient must not receive more than one PBS-subsidised treatment per year, AND
  
  The treatment must be as monotherapy, AND
  
  Patient must have demonstrated compliance with, and an ability to tolerate this therapy.
  
  Treatment criteria:
  
  Must be treated by a neurologist.
  
  Note
  
  Neurologists prescribing PBS-subsidised alemtuzumab must be registered with the Lemtrada monitoring program.
  
  Special Pricing Arrangements apply.
  
  No increase in the maximum quantity or number of units may be authorised.
  
  No increase in the maximum number of repeats may be authorised.

- **ALEMTUZUMAB**
  
  Authority required (STREAMLINED)

  4834
  
  Multiple sclerosis
  
  Treatment Phase: Initial
  
  Clinical criteria:
  
  The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR
  
  The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient, AND
  
  The treatment must be as monotherapy, AND
  
  Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to the multiple sclerosis, in the preceding 2 years, AND
  
  Patient must be ambulatory (without assistance or support).
  
  Treatment criteria:
  
  Must be treated by a neurologist.
  
  Where applicable, the date of the magnetic resonance imaging scan must be provided with the authority application.
  
  Note
  
  Neurologists prescribing PBS-subsidised alemtuzumab must be registered with the Lemtrada monitoring program.
  
  Special Pricing Arrangements apply.
  
  No increase in the maximum quantity or number of units may be authorised.
  
  No increase in the maximum number of repeats may be authorised.

- **ECULIZUMAB**
  
  Authority required
  
  Atypical haemolytic uraemic syndrome (aHUS)
  
  Treatment Phase: Initial treatment 1 – New patient – Balance of Supply
  
  Clinical criteria:
  
  Patient must have received PBS-subsidised initial supply of eculizumab for this condition, AND
Patient must have ADAMTS-13 activity of greater than or equal to 10% on a blood sample, **AND**
Patient must not receive more than 20 weeks supply under this restriction.

**Treatment criteria:**
Must be treated by a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist, or, must be in consultation with a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist.

ADAMTS-13 activity result must have been submitted to the Department of Human Services. In the case that a sample for ADAMTS-13 activity taken prior to plasma exchange or infusion was not available at the time of application for Initial Treatment 1 New Patient, ADAMTS-13 activity must have been measured 1-2 weeks following the last plasma exchange or infusion, and must have been submitted to the Department of Human Services within 27 days of commencement of eculizumab. The date and time that the sample for the ADAMTS-13 assay was collected, and the dates and times of the last, if any, plasma exchange or infusion that was undertaken in the two weeks prior to collection of the ADAMTS-13 assay must also have been provided to Department of Human Services.

**Note**
Serial haematological results (every 3 months while the patient is receiving treatment) must be provided with every subsequent application for treatment. This will assist DHS in the consideration of the patient’s eligibility for further PBS subsidised treatment.

At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug for 4 weeks and up to 4 repeats, according to the specified dosage in the approved Product Information (PI).

Applications for treatment with eculizumab where the dose and dosing frequency exceeds that specified in the approved PI will not be approved.

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

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

Written applications for authority to prescribe must be submitted to Department of Human Services. Human Services will then contact the prescriber by telephone.

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**Eculizumab 300 mg/30 mL injection, 1 x 30 mL vial**

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**ECULIZUMAB**

**Authority required**
Atypical haemolytic ureaemic syndrome (aHUS)

**Treatment Phase:** Initial treatment 1 – New patient

**Clinical criteria:**
Patient must have active and progressing thrombotic microangiopathy (TMA), **AND**
Patient must have ADAMTS-13 activity of greater than or equal to 10% on a blood sample taken prior to plasma exchange or infusion; or, if ADAMTS-13 activity was not collected prior to plasma exchange or infusion, patient must have platelet counts of greater than 30x10^9/L and a serum creatinine of greater than 150 mol/L, **AND**
Patient must have a confirmed negative STEC (Shiga toxin-producing E.Coli) result if the patient has had diarrhoea in the preceding 14 days, **AND**
Patient must have clinical features of active organ damage or impairment, **AND**
Patient must not receive more than 4 weeks of treatment under this restriction.

**Treatment criteria:**
Must be treated by a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist, or, must be in consultation with a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist.

Evidence of active and progressing TMA is defined by the following:

1. a platelet count of less than 150x10^9/L; and evidence of two of the following:
   i. presence of schistocytes on blood film;
   ii. low or absent haptoglobin;
   iii. lactate dehydrogenase (LDH) above normal range;

OR

2. tissue biopsy confirming TMA in patients who don’t have evidence of platelet consumption and haemolysis; **AND**

3. evidence of at least one of the following clinical features of active TMA-related organ damage or impairment is defined as below:
   a. kidney impairment as demonstrated by one of the following:
      i. a decline in estimated Glomerular Filtration Rate (eGFR) of greater than 20% in a patient who has pre-existing kidney impairment; and/or
      ii. a serum creatinine (sCr) of greater than the upper limit of normal (ULN) in a patient who has no history of pre-existing kidney impairment; or
   b. a sCr of greater than the age-appropriate ULN in paediatric patients; or
   c. onset of TMA-related neurological impairment;
   d. onset of TMA-related gastrointestinal impairment;
   e. onset of TMA-related cardiac impairment;
Schedule of Eculizumab

eculizumab 300 mg/30 mL injection, 1 x 30 mL vial

10191J

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**ECULIZUMAB**

**Authority required**

- Atypical haemolytic uraemic syndrome (aHUS)

**Clinical criteria:**

Patient must have received 24 weeks therapy under the initial restriction with PBS subsidised eculizumab for this condition, AND

Patient must have demonstrated on-going treatment response of PBS-subsidised eculizumab treatment for this condition, AND

Patient must not have experienced treatment failure with eculizumab including PBS-subsidised eculizumab for this condition, AND

Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

**Treatment criteria:**

Must be treated by a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist, or, must be in consultation with a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist.

A treatment response is defined as:

1. Normalisation of haematology as demonstrated by at least 2 of the following: platelet count, haptoglobin, and LDH; AND
(2) One of the following:
   a) An increase in eGFR of > 25% from baseline, where the baseline is the eGFR measurement immediately prior to commencing treatment with eculizumab or
   b) an eGFR within +/- 25% from baseline; or
   c) an avoidance of dialysis-dependence but worsening of kidney function with a reduction in eGFR 25% from baseline.

PBS-subsidised treatment with eculizumab will not be permitted if a patient has experienced treatment failure.

A treatment failure is defined as a patient who is:
   (1) dialysis-dependent at the time of application and has failed to demonstrate significant resolution of extra-renal complications if originally presented; or
   (2) on dialysis and has been on dialysis for 4 months of the previous 6 months while receiving PBS-subsidised eculizumab and has failed to demonstrate significant resolution of extra-renal complications if originally presented.

Serial haematological results (every 3 months while the patient is receiving treatment) must be provided.

The authority application must be in writing and must include:
   (1) A completed authority prescription form; and
   (2) A completed aHUS eculizumab Authority Application Supporting Information Form for Continuing treatment; and
   (3) A copy of a current Certificate of vaccination; and
   (4) A measurement of body weight at the time of application; and
   (5) Evidence that the patient has had a treatment response including haematological results of no more than 1 week old at the time of application; and
   (6) Evidence that the patient has not experienced treatment failure, including a supporting statement with clinical evidence that the patient does not require dialysis, unless the indication for continuing eculizumab is severe extra-renal complications that have significantly improved; and
   (7) If the indication for continuing eculizumab is severe extra-renal complications, then a supporting statement with clinical evidence that any initial extra-renal complications of TMA have significantly improved is required.

**Authority required**

Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Continuing treatment – beyond initial 48 weeks of treatment

**Clinical criteria:**

Patient must have received 48 weeks of treatment under Initial treatment—New patient, Initial treatment—Balance of supply and Continuing treatment—New patient with PBS-subsidised eculizumab for this condition, **AND**

Patient must have demonstrated on-going treatment response with PBS-subsidised eculizumab for this condition, **AND**

Patient must not have ever experienced treatment failure with eculizumab including PBS-subsidised eculizumab for this condition, **AND**

Patient must have a TMA-related cardiomyopathy as evidenced by left ventricular ejection fraction < 40%; OR

Patient must have severe TMA-related neurological impairment; OR

Patient must have severe TMA-related gastrointestinal impairment; OR

Patient must have severe TMA-related pulmonary impairment; OR

Patient must have grade 4 or 5 chronic kidney disease (eGFR of less than 30 ml/min), **AND**

Patient must not receive more than 24 weeks of treatment under this restriction.

**Treatment criteria:**

Must be treated by a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist, or, must be in consultation with a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist.

A treatment response is defined as:
   (1) Normalisation of haematology as demonstrated by at least 2 of the following: platelet count, haptoglobin, and LDH; AND
   (2) One of the following:
       a) An increase in eGFR of > 25% from baseline, where the baseline is the eGFR measurement immediately prior to commencing treatment with eculizumab or
       b) an eGFR within +/- 25% from baseline; or
       c) an avoidance of dialysis-dependence but worsening of kidney function with a reduction in eGFR 25% from baseline.

PBS-subsidised treatment with eculizumab will not be permitted if a patient has experienced treatment failure. A treatment failure is defined as a patient who is:
   (1) dialysis-dependent at the time of application and has failed to demonstrate significant resolution of extra-renal complications if originally presented; or
   (2) on dialysis and has been on dialysis for 4 months of the previous 6 months while receiving PBS-subsidised eculizumab and has failed to demonstrate significant resolution of extra-renal complications if originally presented.

Serial haematological results (every 3 months while the patient is receiving treatment) must be provided with every subsequent application for treatment. This will assist DHS in the consideration of the patient’s eligibility for further PBS subsidised treatment.

The authority application must be in writing and must include:
   (1) A completed authority prescription form; and
   (2) A completed aHUS eculizumab Authority Application Supporting Information Form for Continuing treatment; and
   (3) A copy of a current Certificate of vaccination; and
   (4) A measurement of body weight at the time of application; and
   (5) A supporting statement with clinical evidence of severe TMA-related cardiomyopathy (including current LVEF result), neurological impairment, gastrointestinal impairment or pulmonary impairment; and
Schedule of Pharmaceutical Benefits

(6) Evidence that the patient has had a treatment response including haematological results of no more than 1 month old at the time of application (platelet count, haptoglobin and LDH); and an eGFR level of no more than 1 month old at the time of application; and

(7) Evidence that the patient has not experienced treatment failure, including a supporting statement with clinical evidence that the patient does not require dialysis, unless the indication for continuing eculizumab is severe extra-renal complications that have significantly improved; and

(8) If the indication for continuing eculizumab is severe extra-renal complications, then a supporting statement with clinical evidence that any initial extra-renal complications of TMA have significantly improved is required.

**Authority required**

Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Initial treatment 2 – Recomencement of treatment after an initial 48-week period

**Clinical criteria:**

Patient must have received Initial treatment 2 and eculizumab for this condition, AND

Patient must have demonstrated treatment response to previous 48 weeks of treatment with PBS-subsidised eculizumab for this condition, AND

Patient must have the following clinical conditions:

(i) either significant haemolysis as measured by low/absent haptoglobin; or presence of schistocytes on the blood film; or lactate dehydrogenase (LDH) above normal; AND

(ii) either platelet consumption as measured by either 25% decline from patient baseline or thrombocytopenia (platelet count <150 x 10^9/L) OR

(iii) TMA-related organ impairment including on recent biopsy.

Patient must not have ever experienced treatment failure with eculizumab including PBS-subsidised eculizumab for this condition, AND

Patient must have demonstrated ongoing treatment response to the previous 24 weeks of PBS-subsidised eculizumab treatment.

**Treatment criteria:**

Must be treated by a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist, or, must be in consultation with a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist.

A treatment response is defined as:

(1) Normalisation of haemoglobin as demonstrated by at least 2 of the following: platelet count, haptoglobin, and LDH; AND

(2) One of the following:

a) An increase in eGFR of > 25% from baseline, where the baseline is the eGFR measurement immediately prior to commencing treatment with eculizumab or

b) an eGFR within +/- 25% from baseline; or

c) an avoidance of dialysis-dependence but worsening of kidney function with a reduction in eGFR 25% from baseline.

PBS-subsidised treatment with eculizumab will not be permitted if a patient has experienced treatment failure. A treatment failure is defined as a patient who is:

(1) dialysis-dependent at the time of application and has failed to demonstrate significant resolution of extra-renal complications if originally presented; or

(2) on dialysis and has been on dialysis for 4 months of the previous 6 months while receiving PBS-subsidised eculizumab and has failed to demonstrate significant resolution of extra-renal complications if originally presented.

Serial haematological results (every 3 months while the patient is receiving treatment) must be provided with every subsequent application for treatment. This will assist DHS in the consideration of the patient’s eligibility for further PBS subsidised treatment.

The authority application must be in writing and must include:

(1) A completed authority prescription form(s); and

(2) A completed aHUS eculizumab Authority Application Supporting Information Form for Initial treatment 2 - Recomencement of treatment after an initial 48-week period; and

(3) A signed patient acknowledgement or an acknowledgement signed by a parent or authorised guardian, if applicable; and

(4) A copy of a current Certificate of vaccination; and

(5) A measurement of body weight at the time of application, and

(6) A supporting statement with clinical evidence of TMA-related organ damage including current (within one week of application) haematological results (platelet count, haptoglobin and LDH), eGFR level, and, if applicable, on recent biopsy;

(7) Evidence that the patient has had a treatment response to their previous treatment with eculizumab; and

(8) Evidence that the patient has not experienced treatment failure, including a supporting statement with clinical evidence that the patient does not require dialysis, unless the indication for continuing eculizumab is severe extra-renal complications that have significantly improved; and

(9) If the indication for continuing eculizumab is severe extra-renal complications, then a supporting statement with clinical evidence that any initial extra-renal complications of TMA have significantly improved is required.

**Note**

A raise in LDH alone is not a sufficient reason to recommence eculizumab, but thrombocytopenia with one marker of haemolysis (such as raised LDH, presence of schistocytes, or low/absence of haptoglobin) is an accepted reason to consider re-commencement of eculizumab treatment.

Kidney transplantation/dialysis is not a contraindication to recommencement of eculizumab treatment.

**Authority required**

Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Continuing treatment – following recommencement of treatment after an initial 48-week period

**Clinical criteria:**

Patient must have received Initial treatment 2 - recommencement of treatment after an initial 48-week period with PBS-subsidised eculizumab for this condition, AND

Patient must have demonstrated ongoing treatment response to the previous 24 weeks of PBS-subsidised eculizumab for this condition, AND
Patient must not have experienced treatment failure with eculizumab including PBS-subsidised eculizumab for this condition, AND
Patient must not receive more than 24 weeks of treatment under this restriction.

Treatment criteria:
Must be treated by a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist, or, must be in consultation with a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist.

A treatment response is defined as:
1. Normalisation of haematology as demonstrated by at least 2 of the following: platelet count, haptoglobin, and LDH; AND
2. One of the following:
   a. An increase in eGFR of > 25% from baseline, where the baseline is the eGFR measurement immediately prior to commencing treatment with eculizumab or
   b. An eGFR within +/- 25% from baseline; or
   c. An avoidance of dialysis-dependence but worsening of kidney function with a reduction in eGFR 25% from baseline.

Therefore PBS-subsidised treatment with eculizumab will not be permitted if a patient has experienced treatment failure. A treatment failure is defined as a patient who is:
1. Dialysis-dependent at the time of application and has failed to demonstrate significant resolution of extra-renal complications if originally presented; OR
2. On dialysis and has been on dialysis for 4 months of the previous 6 months while receiving PBS-subsidised eculizumab and has failed to demonstrate significant resolution of extra-renal complications if originally presented.

Serial haematological results (every 3 months while the patient is receiving treatment) must be provided with every subsequent application for treatment. This will assist DHS in the consideration of the patient’s eligibility for further PBS subsidised treatment.

The authority application must be in writing and must include:
1. A completed authority prescription form; and
2. A completed aHUS eculizumab Authority Application Supporting Information Form for Continuing treatment; and
3. A copy of a current Certificate of vaccination; and
4. A measurement of body weight at the time of application; and
5. Evidence that the patient has had a treatment response including haematological results of no more than 1 week old at the time of application (platelet count, haptoglobin and LDH); and an eGFR level of no more than 1 week old at the time of application; and
6. Evidence that the patient has not experienced treatment failure, including a supporting statement with clinical evidence that the patient does not require dialysis, unless the indication for continuing eculizumab is severe extra-renal complications that have significantly improved; and
7. If the indication for continuing eculizumab is severe extra-renal complications, then a supporting statement with clinical evidence that any initial extra-renal complications of TMA have significantly improved is required.

Note
At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug for 4 weeks and up to 5 repeats, according to the specified dosage in the approved Product Information (PI).

Applications for treatment with eculizumab where the dose and dosing frequency exceeds that specified in the approved PI will not be approved.

Authority required
Atypical haemolytic uraemic syndrome (aHUS)
Treatment Phase: Initial 3 - Grandfather eculizumab patients

Clinical criteria:
Patient must have had documented history of active and progressing thrombotic microangiopathy (TMA), AND
Patient must have had documented an ADAMTS-13 activity level consistent with a diagnosis of aHUS, AND
Patient must have received treatment with eculizumab for this condition prior to 1 December 2014, AND
Patient must have received treatment with eculizumab within the last 6 months at the time of application, AND
Patient must have demonstrated on-going treatment response as specified in the Continuing treatment New Patient criteria for PBS-subsidised treatment with eculizumab for this condition, if the patient has received adequate therapy in order to demonstrate response, AND
Patient must not have experienced treatment failure with eculizumab for this condition as specified in the Continuing treatment New Patient criteria for PBS-subsidised treatment with eculizumab for this condition, AND
Patient must have clinical features of active organ damage or impairment at the time of a diagnosis of aHUS episode that required treatment with eculizumab, AND
Patient must not receive more than 24 weeks of treatment under this restriction.

Treatment criteria:
Must be treated by a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist, or, must be in consultation with a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist.

Evidence of active and progressing TMA is defined by the following:
1. A platelet count of less than 150x10^9/L; and evidence of two of the following:
   i. Presence of schistocytes on blood film;
   ii. Low or absent haptoglobin;
   iii. Lactate dehydrogenase (LDH) above normal range;
OR
2. Tissue biopsy confirming TMA in patients who do not have evidence of platelet consumption and haemolysis; AND
(3) evidence of at least one of the following clinical features of active TMA-related organ damage or impairment is defined as below:

(a) kidney impairment as demonstrated by one of the following:
   (i) a decline in estimated Glomerular Filtration Rate (eGFR) of greater than 20% in a patient who has pre-existing kidney impairment; and/or
   (ii) a serum creatinine (sCr) of greater than the upper limit of normal (ULN) in a patient who has no history of pre-existing kidney impairment; or
   (iii) a sCr of greater than the age-appropriate ULN in paediatric patients; or

(b) tissue biopsy confirming TMA in patients who don’t have evidence of platelet consumption and haemolysis;

(c) evidence of at least one of the following clinical features of active TMA

   (i) presence of schistocytes on blood film;
   (ii) low or absent haptoglobin;
   (iii) lactate dehydrogenase (LDH) above normal range;

   OR

(b) tissue biopsy confirming TMA in patients who don’t have evidence of platelet consumption and haemolysis; AND

(c) evidence of at least one of the following clinical features of active TMA-related organ damage or impairment is defined as below:

(a) kidney impairment as demonstrated by one of the following:
   (i) a decline in estimated Glomerular Filtration Rate (eGFR) of greater than 20% in a patient who has pre-existing kidney impairment; and/or
   (ii) a serum creatinine (sCr) of greater than the upper limit of normal (ULN) in a patient who has no history of pre-existing kidney impairment; or
   (iii) a sCr of greater than the age-appropriate ULN in paediatric patients; or

(b) onset of TMA-related neurological impairment;

(c) onset of TMA-related cardiac impairment;

(d) onset of TMA-related gastrointestinal impairment;

(e) onset of TMA-related pulmonary impairment

A treatment response is defined as:

(1) Normalisation of haematology as demonstrated by at least 2 of the following: platelet count, haptoglobin, and LDH; AND

(2) One of the following:
   a) An increase in eGFR of > 25% from baseline, where the baseline is the eGFR measurement immediately prior to commencing treatment with eculizumab or
   b) an eGFR within +/- 25% from baseline; or
   c) an avoidance of dialysis-dependence but worsening of kidney function with a reduction in eGFR 25% from baseline.

PBS-subsidised treatment with eculizumab will not be permitted if a patient has experienced treatment failure. A treatment failure is defined as a patient who is:

(1) dialysis-dependent at the time of application and has failed to demonstrate significant resolution of extra-renal complications if originally presented; or

(2) on dialysis and has been on dialysis for 4 months of the previous 6 months while receiving PBS-subsidised eculizumab and has failed to demonstrate significant resolution of extra-renal complications if originally presented.

The authority application must be in writing and must include:

(1) A completed authority prescription form; and

(2) A completed aHUS eculizumab Authority Application Supporting Information Form for initial PBS-subsidised eculizumab treatment; and

(3) A signed patient acknowledgement or an acknowledgement signed by a parent or authorised guardian, if applicable; and

(4) A copy of a current Certificate of vaccination; and

(5) A measurement of body weight at the time of application; and

(6) The result of ADAMTS-13 activity on a blood sample at the time this condition was diagnosed; and

(7) Evidence that the patient has previously received treatment with eculizumab for this condition within the last 6 months at the time of application; and

(8) Evidence that the patient has had a treatment response including haematological results of no more than 1 week old at the time of application (platelet count, haptoglobin and LDH); and an eGFR level of no more than 1 week old at the time of application; or clinical reasons to justify the commencing of treatment with PBS-subsidised eculizumab; and

(9) Evidence that the patient has not experienced treatment failure, including a supporting statement with clinical evidence that the patient does not require dialysis, unless the indication for continuing eculizumab is severe extra-renal complications that have significantly improved; and

(10) A confirmed negative STEC (Shiga toxin-producing E.Coli) result if available at the time of diagnosis; or evidence that the diagnosis was not associated with an infection; and

(11) Where available in the week prior to commencing eculizumab results demonstrating:

(a) a platelet count of less than 150 x10^9/L; and evidence of two of the following:
   (i) presence of schistocytes on blood film;
   (ii) low or absent haptoglobin;
   (iii) lactate dehydrogenase (LDH) above normal range;

   OR

(b) tissue biopsy confirming TMA in patients who don’t have evidence of platelet consumption and haemolysis; AND

(c) evidence of at least one of the following clinical features of active TMA-related organ damage or impairment is defined as below:

(a) kidney impairment as demonstrated by one of the following:
   (i) a decline in estimated Glomerular Filtration Rate (eGFR) of greater than 20% in a patient who has pre-existing kidney impairment; and/or
   (ii) a serum creatinine (sCr) of greater than the upper limit of normal (ULN) in a patient who has no history of pre-existing kidney impairment; or
   (iii) a sCr of greater than the age-appropriate ULN in paediatric patients; or

(b) onset of TMA-related neurological impairment;

(c) onset of TMA-related cardiac impairment;

(d) onset of TMA-related gastrointestinal impairment;

(e) onset of TMA-related pulmonary impairment; and

(12) Where available within one month prior to commencement of eculizumab, evidence of active and progressing TMA, including pathology results where relevant. Evidence of the onset of TMA-related neurological, cardiac, gastrointestinal or pulmonary impairment requires a supporting statement with clinical evidence in patient records.
Serial haematological results (every 3 months while the patient is receiving treatment) must be provided with every subsequent application for treatment. This will assist DHS in the consideration of the patient’s eligibility for further PBS subsidised treatment.

**Note**

**WARNING:** Eculizumab increases the risk of meningococcal infections (septicaemia and/or meningitis)

> Vaccinate patients with a meningococcal vaccine at least 2 weeks prior to receiving the first dose of eculizumab; revaccinate according to current medical guidelines for vaccine use
> Patients less than 2 years of age and those who are treated with eculizumab less than 2 weeks after receiving a meningococcal vaccine must receive treatment with appropriate prophylactic antibiotics until 2 weeks after vaccination.

Monitor patients for early signs of meningococcal infections, evaluate immediately if infection is suspected, and treat with antibiotics if necessary.

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

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

Written applications for authority to prescribe must be submitted to Department of Human Services. Human Services will then contact the prescriber by telephone.

**Eculizumab 300 mg/30 mL injection, 1 x 30 mL vial**

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**EVEROLIMUS**

**Caution**

Careful monitoring of patients is mandatory.

**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

**Everolimus 1 mg tablet, 60**

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**MYCOPHENOLATE**

**Caution**

Careful monitoring of patients is mandatory.

**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
**MYCOPHENOLATE**

*Caution*

Careful monitoring of patients is mandatory.

**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.

*Note*

Management includes initiation, stabilisation and review of therapy as required.

---

**mycophenolate 180 mg tablet: enteric, 120 tablets**

**9503E**

Max Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer
---|---|---|---|---
2 | 5 | .. | *217.62 | Myfortic [NV]

---

**mycophenolate 360 mg tablet: enteric, 120 tablets**

**9504F**

Max Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer
---|---|---|---|---
2 | 5 | .. | *435.22 | Myfortic [NV]

---

**MYCOPHENOLATE**

*Caution*

Careful monitoring of patients is mandatory.

**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

*Note*

For item codes 9501C and 1839T, pharmaceutical benefits that have the form capsule 250 mg are equivalent for the purposes of substitution.

---

**mycophenolate Capsule 250 mg, 50**

**1839T**

Max Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer
---|---|---|---|---
12 | 5 | .. | *544.08 | Ceptolate [AF]

---

**mycophenolate mofetil 250 mg capsule, 100**

**9501C**

Max Qty Packs | No. of Rpts | Premium $ | DPMQ $ | Brand Name and Manufacturer
---|---|---|---|---
6 | 5 | .. | *544.08 | Mycophenolate Sandoz [SZ]

---

**NATALIZUMAB**

*Caution*
Progressive multifocal leukoencephalopathy has been reported with this drug.

**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

**Note**

Neurologists prescribing natalizumab under the PBS listing must be registered with the Tysabri Australian Prescribing Program.

Special Pricing Arrangements apply.

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**natalizumab 300 mg/15 mL injection, 1 x 15 mL vial**

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**SIROLIMUS**

**Caution**

Careful monitoring of patients is mandatory.

**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

---

**sirolimus 1 mg tablet, 100**

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**sirolimus 1 mg/mL oral liquid, 60 mL**

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**sirolimus 2 mg tablet, 100**

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**sirolimus 500 microgram tablet, 100**

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**Tumor necrosis factor alpha (TNF-) inhibitors**

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**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**
- 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.

**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).

**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 12 months) or Initial 2 (change or recommencement of treatment after break of less than 12 months) – balance of supply

**Clinical criteria:**

Patient must have received insufficient adalimumab therapy under the Initial 1 (new patient or patient recommencing treatment after break of more than 12 months) restriction to complete 16 weeks treatment; OR

Patient must have received insufficient adalimumab therapy under the Initial 2 (change or recommencement of treatment after break of less than 12 months) restriction to complete 16 weeks treatment, AND

The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Treatment criteria:**

Must be treated by a paediatric rheumatologist; OR

Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

**Note**

Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment

**Clinical criteria:**

Patient must have a documented history of severe active juvenile idiopathic arthritis, AND

Patient must have demonstrated an adequate response to treatment with adalimumab, AND

Patient must have received adalimumab as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment in this treatment cycle, AND

Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

**Treatment criteria:**

Must be treated by a rheumatologist; OR

Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

For the purposes of this restriction ‘biological disease modifying anti-rheumatic drug’ and ‘bDMARD’ mean adalimumab, etanercept or tocilizumab.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:
   (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
   (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurement of joint count submitted with the initial treatment application.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and
(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.
At the time of authority application, medical practitioners must request the appropriate number of injections of appropriate strength, based on the weight of the patient, to provide sufficient for two doses. Up to a maximum of 5 repeats will be authorised.

All applications for continuing treatment with adalimumab must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with adalimumab, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with adalimumab.

If a patient fails to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) they will not be eligible to receive further PBS-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

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.

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

**adalimumab 20 mg/0.4 mL injection, 2 x 0.4 mL syringes**

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**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges**

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**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes**

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**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**

Population criteria:
- Patient must not receive more than 16 weeks of treatment under this restriction.

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 4 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.

**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).

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 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
Treatment Phase: Continuing treatment

Clinical criteria:
Patient must have a documented history of severe active juvenile idiopathic arthritis, AND
Patient must have demonstrated an adequate response to treatment with etanercept, AND
Patient must have received etanercept as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment in this treatment cycle, AND
Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

Treatment criteria:
Must be treated by a rheumatologist; OR
Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurement of joint count submitted with the initial treatment application.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners must request the appropriate number of injections to provide sufficient for four weeks of treatment. Up to a maximum of 5 repeats will be authorised.

All applications for continuing treatment with etanercept must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with etanercept, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with etanercept.

If a patient fails to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle.

**Note**

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826

HOBART TAS 7001

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 equitably 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 of 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 Injection 50 mg in 1 mL single use auto-injector, 4, 1

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ETANERCEPT Injections 50 mg in 1 mL single use pre-filled syringes, 4, 1

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Etanercept 25 mg injection [4 x 25 mg vials] (& inert substance diluent [4 x 1 mL syringes], 1 pack

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**INFLIXIMAB**

**Authority required (STREAMLINED)**

**4524**

Acute severe ulcerative colitis

**Clinical criteria:**

- Patient must have received an infusion of infliximab for the treatment of this condition as a hospital inpatient no more than two weeks prior to the date of the authority application, **AND**
- Patient must be an adult aged 18 years or older, and prior to initiation of infliximab treatment in hospital must have been experiencing six or more bloody stools per day, plus at least one of the following: (i) Temperature greater than 37.8 degrees Celsius; (ii) Pulse rate greater than 90 beats per minute; (iii) Haemoglobin less than 105 g/L; (iv) Erythrocyte sedimentation rate greater than 30 mm/h；OR
- Patient must be a child aged 6 to 17 years inclusive, and prior to initiation of infliximab treatment in hospital must have had a Paediatric Ulcerative Colitis Activity Index (PUCAI) greater than or equal to 65, with the diagnosis confirmed by a gastroenterologist, or a consultant physician as specified below, **AND**
- Patient must have failed to achieve an adequate response to at least 72 hours treatment with intravenous corticosteroids prior to initiation of infliximab treatment in hospital.

**Population criteria:**

- Patient must be 6 years of age or older.

**Treatment criteria:**

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology, or general medicine specialising in gastroenterology].

For adults aged 18 years or older, failure to achieve an adequate response to intravenous corticosteroid treatment is defined by the Oxford criteria where:

(i) If assessed on day 3, patients pass 8 or more stools per day or 3 or more stools per day with a C-reactive protein (CRP) greater than 45 mg/L
(ii) If assessed on day 7, patients pass 3 or more stools per day with visible blood.

For children aged 6 to 17 years, failure to achieve an adequate response to intravenous corticosteroids means a PUCAI score greater than 45 at 72 hours.

At the time of authority application, prescribers should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg.

Before administering infliximab to a child aged 6 to 17 years, the treating clinician must have consulted with a paediatric gastroenterologist or with an institution experienced in performance of paediatric colectomy. The name of the specialist or institution must be included in the patient’s medical records.

Evidence that the patient meets the PBS restriction criteria must be recorded in the patient’s medical records.

**Note**

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

**INFLIXIMAB**

**Authority required**

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:
ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

(i) a tapered course of steroids, starting at a dose of at least 1 mg per kg or 40 mg (whichever is the lesser) prednisolone (or equivalent), over a 6 week period;
(ii) an 8 week course of enteral nutrition;
(iii) immunosuppressive therapy including:
   — azathioprine at a dose of at least 2 mg per kg daily for 3 or more months; or
   — 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months; or
   — methotrexate at a dose of at least 10 mg per square metre weekly for 3 or more months.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of the accepted toxicities including severity can be found on the Medicare Australia website (www.medicareaustralia.gov.au).

The following initiation criterion indicates failure to achieve an adequate response and must be demonstrated in all patients at the time of the application:

(a) severity of disease activity which results in a Paediatric Crohn Disease Activity Index (PCDAI) Score greater than or equal to 30 as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

(b) The most recent PCDAI assessment must be no more than 1 month old at the time of application.

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

Applications for authorisation must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) the completed current Paediatric Crohn Disease Activity Index (PCDAI) calculation sheet including the date of assessment of the patient's condition; and
(ii) details of previous systemic drug therapy [dosage, date of commencement and duration of therapy], or dates of enteral nutrition; and
(iii) the signed patient acknowledgement.

A maximum quantity and number of repeats to provide for an initial course of infliximab consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of 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, 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
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 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) 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 timeframe s, 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 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, 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 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

TREATMENT OF COMPLEX REFRACTORY FISTULISING CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab and infliximab for patients with complex refractory fistulising Crohn disease. Where the term ‘tumour necrosis factor (TNF) alfa antagonist’ appears in the following NOTES and restrictions, it refers to adalimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 2 TNF-alfa antagonists at any 1 time.

From 1 April 2011, under the PBS, all patients will be able to commence a treatment cycle where they may trial each PBS-subsidised TNF-alfa antagonist without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a TNF-alfa antagonist while they continue to show a response to therapy.

A patient who received PBS-subsidised TNF-alfa antagonist treatment prior to 1 April 2011 is considered to be in their first cycle as of 1 April 2011. 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 that 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. 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.

(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.

infliximab 100 mg injection, 1 x 100 mg vial

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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:

(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

Schedule of Pharmaceutical Benefits 907
(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 approval for initial authority applications, or for treatment that would otherwise extend the initial treatment period beyond 22 weeks.

A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment

**Authority required**

Initial or re-Treatment [Initial 2, Whole body (Received prior biological agent under PBS)]

Treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over who:

(a) have a documented history of severe chronic plaque psoriasis; and
(b) have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle; and
(c) have not failed PBS-subsidised therapy with infliximab for the treatment of this condition in the current Treatment Cycle.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and
(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and
(ii) details of prior biological treatment, including dosage, date and duration of treatment.

Applications for patients who have demonstrated a response to PBS-subsidised infliximab treatment within this Treatment Cycle and who wish to re-commence infliximab treatment within the same Cycle following a break in therapy, will only be approved where evidence of the patient's response to their most recent course of PBS-subsidised infliximab treatment has been submitted to Medicare Australia within 1 month of cessation of treatment.

A maximum of 22 weeks of treatment with infliximab will be authorised under this restriction.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 22 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be
granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period beyond 22 weeks.

A PASI assessment of the patient's response to this course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment.

Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may re-commence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

**Authority required**

Continuing treatment (Whole body)

Continuing PBS-subsidised treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over:

(a) who have a documented history of severe chronic plaque psoriasis; and
(b) whose most recent course of PBS-subsidised biological treatment for this condition in this Treatment Cycle was with infliximab; and
(c) who have demonstrated an adequate response to their most recent course of treatment with infliximab.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the pre-biological treatment baseline value for this Treatment Cycle.

This assessment must be provided to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with infliximab, the assessment of response must be after a minimum of 12 weeks of treatment with an initial course.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and
(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) the completed Psoriasis Area and Severity Index (PASI) calculation sheet along with the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 1 month old at the time of application.

Application 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.

(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 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 withdrawal so that a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline

**Authority required**

Initial or re-Treatment [Initial 2, Face, hand, foot (Received prior biological agent under PBS)]

Treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over who:

(a) have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot; and

(b) have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle; and

(c) have not failed PBS-subsidised therapy with infliximab for the treatment of this condition in the current Treatment Cycle.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and

(ii) details of prior biological treatment, including dosage, date and duration of treatment.
Applications for patients who have demonstrated a response to PBS-subsidised infliximab treatment within this Treatment Cycle and who wish to re-commence infliximab treatment within the same Cycle following a break in therapy, will only be approved where evidence of the patient's response to their most recent course of PBS-subsidised infliximab treatment has been submitted to Medicare Australia within 1 month of cessation of treatment. A maximum of 22 weeks of treatment with infliximab will be authorised under this restriction. At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 22 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period beyond 22 weeks.

A PASI assessment of the patient's response to this course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.

It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline. Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may re-commence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

**Authority required**

Continuing treatment (Face, hand, foot)

Continuing PBS-subsidised treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over:

(a) who have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot; and
(b) whose most recent course of PBS-subsidised biological treatment for this condition in this Treatment Cycle was with infliximab; and
(c) who have demonstrated an adequate response to treatment with infliximab.

An adequate response to infliximab treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the pre-biological treatment baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the pre-biological treatment baseline value.

This assessment must be provided to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with infliximab, the assessment of response must be after a minimum of 12 weeks of treatment with an initial course.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams along with the date of the assessment of the patient's condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

The most recent PASI assessment must be no more than 1 month old at the time of application. A maximum of 24 weeks of treatment with infliximab will be authorised under this restriction. At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for continuing authority applications, or for treatment that would otherwise extend the treatment period beyond 24 weeks.

A PASI assessment of the patient's response must be conducted within 4 weeks prior to completion of this course of treatment. This assessment, which will be used to determine eligibility for further continuing treatment must be submitted to Medicare Australia no later than 1 month from the date of completion of this course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab. In circumstances where it is not possible to submit a response assessment within these timeframes, please call Medicare Australia on 1800 700 270 to discuss.
It is recommended that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment.

The PASI assessment for continuing treatment must be performed on the same affected area assessed at baseline. Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may re-commence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date after 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

**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.

There are separate restrictions for both the initial and continuing treatment of severe chronic plaque psoriasis after 1 March 2010. Patients for whom a break in PBS-subsidised therapy of less than 5 years duration has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, 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 continued 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.

No applications for increased repeats will be authorised.

infliximab 100 mg injection, 1 x 100 mg vial

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**INFLIXIMAB**

*Authority required*

Moderate to severe ulcerative colitis

*Treatment Phase: Initial treatment (new patient)*

**Clinical criteria:**

Patient must have failed to achieve an adequate response to a 5-aminosalicylate oral preparation in a standard dose for induction of remission for 3 or more months or have intolerance necessitating permanent treatment withdrawal, **AND**

Patient must have failed to achieve an adequate response to azathioprine at a dose of at least 2 mg per kg daily for 3 or more months or have intolerance necessitating permanent treatment withdrawal; **OR**

Patient must have failed to achieve an adequate response to 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months or have intolerance necessitating permanent treatment withdrawal; **OR**

Patient must have failed to achieve an adequate response to a tapered course of oral steroids, starting at a dose of at least 40 mg (for a child, 1 to 2 mg/kg up to 40 mg) prednisolone (or equivalent), over a 6 week period or have intolerance necessitating permanent treatment withdrawal, **AND**

Patient must have a Mayo clinic score greater than or equal to 6 if an adult patient; **OR**

Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score); **OR**

Patient must have a Paediatric Ulcerative Colitis Activity Index (PUCAI) Score greater than or equal to 30 if aged 6 to 17 years.

**Population criteria:**

Patient must be 6 years of age or older.

**Treatment criteria:**

Must be treated by a gastroenterologist (code 87) or a consultant physician (internal medicine specialising in gastroenterology (code 81)) or a consultant physician (general medicine specialising in gastroenterology (code 82)); **OR**

Must be treated by a paediatrician or specialist paediatric gastroenterologist if aged between 6 to 17 years.
Applications for authorisation of initial treatment must be in writing and must include:

(a) a completed authority prescription form; and
(b) a completed Ulcerative Colitis PBS Authority Application - Supporting Information Form which includes the following:
(i) the completed current Mayo clinic or partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) calculation sheet including the date of assessment of the patient's condition; and
(ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and
(iii) the signed patient acknowledgement.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised. All tests and assessments should be performed preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment. The most recent Mayo clinic, partial Mayo clinic or PUCAI score must be no more than 1 month old at the time of application. Patients who fail to achieve a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1, or a PUCAI score less than 10 within the first 12 weeks of receiving this drug for ulcerative colitis, or have failed to maintain a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1, or have failed to maintain a PUCAI score less than 10 (if aged 6 to 17 years) with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug.

A partial Mayo clinic or PUCAI assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated. The patient or guardian (required if patient aged 6 to 17 years) must have signed a patient acknowledgement indicating they understand and acknowledge that the PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment. If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application. If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Patients may qualify for PBS-subsidised treatment under this restriction once only.

**Authority required**

Moderate to severe ulcerative colitis

**Treatment Phase: Initial PBS-subsidised treatment of moderate to severe ulcerative colitis in a patient who has previously received non-PBS-subsidised therapy with this drug (grandfather)**

**Clinical criteria:**

Patient must have been receiving treatment with this drug prior to 1 December 2014, **AND**

Patient must have had a Mayo clinic score greater than or equal to 6 prior to commencing treatment with this drug; **OR**

Patient must have had a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores were both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo score) prior to commencing treatment with this drug; **OR**

Patient must have had a Paediatric Ulcerative Colitis Activity Index (PUCAI) Score greater than or equal to 30 prior to commencing treatment with this drug; **OR**

Patient must have a documented history of moderate to severe refractory ulcerative colitis prior to having commenced treatment with this drug where a Mayo clinic, partial Mayo clinic or PUCAI baseline assessment is not available, **AND**

Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug; **OR**

Patient must have demonstrated or sustained an adequate response to treatment by having a Paediatric Ulcerative Colitis Activity Index (PUCAI) score less than 10 while receiving treatment with this drug if aged 6 to 17 years.

**Population criteria:**

Patient must be 6 years of age or older.

**Treatment criteria:**

Must be treated by a gastroenterologist (code 87) or a consultant physician [internal medicine specialising in gastroenterology (code 81)] or a consultant physician [general medicine specialising in gastroenterology (code 82)]; **OR**

Must be treated by a paediatrician or specialist paediatric gastroenterologist if aged between 6 to 17 years. Applications for authorisation of initial treatment must be in writing and must include:

(a) a completed authority prescription form; and
(b) a completed Ulcerative Colitis PBS Authority Application - Supporting Information Form which includes the following:
(i) the completed current and baseline Mayo clinic or partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) calculation sheet including the date of assessment of the patient's condition and
(ii) the date of commencement of this drug and
(iii) the signed patient acknowledgement.

The current Mayo clinic or partial Mayo clinic or PUCAI assessment must be no more than 1 month old at the time of application. The baseline assessment must be from immediately prior to commencing treatment with this drug. Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain the response.

**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
At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to be sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised. No applications for increased repeats will be authorised.

The patient or guardian (required if patient aged 6 to 17 years) must have signed a patient acknowledgement indicating they understand and acknowledge that the PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment.

Patients may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria.

Note
Where a baseline assessment is not available, please call the Department of Human Services on 1800 700 270 to discuss (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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

Prescribing information (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
Moderate to severe ulcerative colitis
Treatment Phase: Balance of supply

Clinical criteria:
Patient must have received insufficient therapy with this drug under the Initial treatment (new patient) restriction to complete the 3 doses (i.e. the initial infusion regimen at weeks 0, 2 and 6 weeks); OR
Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks of treatment; OR
Patient must have received insufficient therapy with this drug to complete 24 weeks of treatment under the Initial PBS-subsidised treatment restriction for patients who had previously received non-PBS subsidised treatment (Grandfathered patient), AND

The treatment must provide no more than the balance of up to 3 doses (new patients) or 2 repeats (Continuing patients or Grandfathered patients).

Population criteria:
Patient must be 6 years of age or older.

Treatment criteria:
Must be treated by a gastroenterologist (code 87) or a consultant physician [internal medicine specialising in gastroenterology (code 81)] or a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
Must be treated by a paediatrician or specialist paediatric gastroenterologist if aged between 6 to 17 years.

Note
Authority approval for sufficient therapy to complete a maximum of 3 initial doses or 2 repeats may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authority approval for sufficient therapy to complete a maximum of 3 initial doses or 2 repeats should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826

HOBART TAS 7001

Authority required
Moderate to severe ulcerative colitis
Treatment Phase: Continuing treatment

Clinical criteria:
Patient must have previously been issued with an authority prescription for this drug for this condition, AND
Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug; OR
Patient must have demonstrated or sustained an adequate response to treatment by having a Paediatric Ulcerative Colitis Activity Index (PUCAI) score less than 10 while receiving treatment with this drug if aged 6 to 17 years.

Treatment criteria:
Must be treated by a gastroenterologist (code 87) or a consultant physician [internal medicine specialising in gastroenterology (code 81)] or a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
Must be treated by a paediatrician or specialist paediatric gastroenterologist if aged between 6 to 17 years.
Patients who have failed to maintain a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1, or, patients who have failed to maintain a PUCAI score less than 10 (if aged 6 to 17 years) with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain the response. At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised. No applications for increased repeats will be authorised.

Note
Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
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HOBART TAS 7001

Special Pricing Arrangements apply.

infliximab 100 mg injection, 1 x 100 mg vial

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**INFLIXIMAB**

**Authority required**
Active ankylosing spondylitis

**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
(ii) a completed Exercise Program Self Certification Form included in the supporting information form; and
(iii) 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

For details on the appropriate minimum exercise program that will be accepted for the purposes of administering this restriction, please refer to the Department of Human Services website at www.humanservices.gov.au

**Authority required**
Ankylosing spondylitis
Treatment Phase: Initial 2 (change or recommencement for all patients)

**Clinical criteria:**
- Patient must have a documented history of active ankylosing spondylitis, **AND**
- Patient must have received prior PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition in this treatment cycle, **AND**
- Patient must not have failed PBS-subsidised therapy with this drug for this condition in the current treatment cycle, **AND**
- Patient must be eligible to receive further bDMARD therapy.

**Population criteria:**
- Patient must be an adult.

**Treatment criteria:**
Must be treated by a rheumatologist.

Where the most recent course of PBS-subsidised bDMARD treatment was approved under either of the initial treatment restrictions (i.e. for patients with no prior PBS-subsidised bDMARD therapy or, under this restriction, for patients who have received previous PBS-subsidised bDMARD therapy) the patient must have been assessed for response to that course following a minimum of 12 weeks of treatment. These assessments must be provided to the Department of Human Services no later than 4 weeks from the date the course was ceased. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, patients must have been assessed for response, and the assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

The authority application must be made in writing and must include:
- (a) a completed authority prescription form; and
- (b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form.

A maximum of 18 weeks of treatment with this drug will be approved under this criterion.

At the time of authority application, the doctor should request the appropriate number of vials, based on the weight of the patient, to provide for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.

Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised bDMARD was approved in this cycle and the date of the first application under a new cycle.

**Authority required**
Ankylosing spondylitis
Treatment Phase: 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 1 (new patients) restriction to complete 18 weeks treatment, **AND**

The treatment must provide no more than the balance of up to 18 weeks treatment available under the above restrictions.

**Population criteria:**
- Patient must be an adult.

**Treatment criteria:**
- Must be treated by a rheumatologist.

**Note**
Authority approval for sufficient therapy to complete a maximum of 18 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 18 weeks of treatment should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826

HOBART TAS 7001

**Authority required**

Ankylosing spondylitis

Treatment Phase: Continuing treatment

**Clinical criteria:**

Patient must have a documented history of active ankylosing spondylitis, **AND**

Patient must have received this drug as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment in this treatment cycle, **AND**

Patient must have demonstrated an adequate response to treatment with this drug.

**Population criteria:**

Patient must be an adult.

**Treatment criteria:**

Must be treated by a rheumatologist.

An adequate response is defined as an improvement from baseline of at least 2 of the BASDAI and 1 of the following:

(a) an ESR measurement no greater than 25 mm per hour; or

(b) a CRP measurement no greater than 10 mg per L; or

(c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and supplied in all subsequent continuing treatment applications.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form.

All measurements provided must be no more than 1 month old at the time of application.

A maximum of 24 weeks of treatment with this drug will be authorised under this criterion.

At the time of authority application, the doctor should request the appropriate number of vials, based on the weight of the patient, to provide for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.

All applications for continuing treatment with this drug must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment following an initial treatment course it must be made following a minimum of 12 weeks of treatment with this drug. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised bDMARD was approved in this cycle and the date of the first application under a new cycle.

**Note**

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

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

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
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 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

**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**

**infliximab 100 mg injection, 1 x 100 mg vial**

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*INFLIXIMAB*

**Authority required**
- Severe active rheumatoid arthritis

**Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months)**

**Clinical criteria:**
- Patient must have severe active rheumatoid arthritis, **AND**
- Patient must have received no PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition in the previous 24 months, **AND**
- Patient must have not failed previous PBS-subsidised treatment with infliximab for this condition, and have not already failed, or ceased to respond to, PBS-subsidised bDMARD treatment for this condition 5 times, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above, must include at least 3 months continuous treatment with each of at least 2 DMARDs, with one or more of the following DMARDs being used in place of the DMARDs which are contraindicated or not tolerated: (i) azathioprine at a dose of at least 1 mg/kg per day; and/or (ii) cyclosporin at a dose of at least 2 mg/kg/day; and/or (iii) sodium aurothiomalate at a dose of 50 mg weekly, **AND**
- Patient must not receive more than 22 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

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

**Treatment criteria:**
- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab or tocilizumab.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate.

The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.
The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application including severity.

The authority application must be made in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form; and
(3) a signed patient acknowledgement.

At the time of authority application, medical practitioners should request the appropriate number of vials to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 3 mg per kg. Up to a maximum of 3 repeats will be authorised.

Assessment of a patient's response to an initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted no later than 1 month from the date of completion of this initial course of treatment.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

Applications for a patient who has received PBS-subsidised treatment with infliximab and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised infliximab treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised infliximab treatment was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised infliximab treatment was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

If a patient fails to demonstrate a response to treatment with infliximab under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

- an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either
  (a) a total active joint count of at least 20 active (swollen and tender) joints; or
  (b) at least 4 active joints from the following list of major joints:
    (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
    (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Where the baseline joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP is provided with the initial application, the same marker will be used to determine response.

**Note**

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:

- exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose;
- substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial;
- exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy.

Special Pricing Arrangements apply.

**Authority required**

Severe active rheumatoid arthritis

**Clinical criteria:**

Patient must have a documented history of severe active rheumatoid arthritis, **AND**

Patient must have received prior PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition and are eligible to receive further bDMARD therapy, **AND**

Patient must not receive more than 22 weeks of treatment under this restriction, **AND**

The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

**Population criteria:**

Patient must be aged 18 years or older.

**Treatment criteria:**

Patient must be aged 18 years or older.
Must be treated by a rheumatologist; OR
Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab or tocilizumab.

The authority application must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners should request the appropriate number of vials to provide sufficient drug, based on the weight of the patient, for single infusion at a dose of 3 mg per kg. Up to a maximum of 3 repeats will be authorised.

Applications for a patient who has received PBS-subsidised treatment with infliximab and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised infliximab treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised infliximab treatment was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised infliximab treatment was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

If a patient fails to demonstrate a response to a treatment with infliximab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD.

An adequate response to treatment is defined as:
an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;
AND either of the following:
(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:
(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months) or Initial 2 (change or recommencement of treatment after break of less than 24 months) – balance of supply.

Clinical criteria:
Patient must have received insufficient infliximab therapy under the Initial 1 (new patient or patient recommencing treatment after break of more than 24 months) restriction to complete 22 weeks treatment; OR
Patient must have received insufficient infliximab therapy under the Initial 2 (change or recommencement of treatment after break of less than 24 months) restriction to complete 22 weeks treatment, AND
The treatment must provide no more than the balance of up to 22 weeks treatment available under the above restrictions.

**Treatment criteria:**
Must be treated by a rheumatologist; OR
Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Note**

Authority approval for sufficient therapy to complete a maximum of 22 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 22 weeks of treatment should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826

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**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Continuing treatment.

Clinical criteria:
Patient must have a documented history of severe active rheumatoid arthritis, AND
Patient must have demonstrated an adequate response to treatment with infliximab, AND
Patient must have received infliximab as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment, AND
Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction, AND
The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

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

Treatment criteria:
Must be treated by a rheumatologist; OR
Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.
For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab or tocilizumab.
An adequate response to treatment is defined as:
an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;
AND either of the following:
(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:
(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).
Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.
The authority application must be made in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.
At the time of authority application, medical practitioners should request the appropriate number of vials to provide sufficient drug, based on the weight of the patient, for single infusion at a dose of 3 mg per kg. Up to a maximum of 2 repeats will be authorised.
All applications for continuing treatment with infliximab must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with infliximab, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.
Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.
If a patient fails to demonstrate a response to treatment with infliximab under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

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

HOBART TAS 7001
TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab) and the T-cell co-stimulation modulator (abatacept).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.
In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.
A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.
A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of PBS-subsidised therapy under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

1. How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or

(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or

(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or

(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab and tocilizumab, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:

Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:

A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to that particular treatment.

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.

- Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Continuing Treatment – balance of supply.

**Clinical criteria:**

- Patient must have received insufficient infliximab therapy under the Continuing Treatment restriction to complete 24 weeks treatment, AND
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Note**

Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:

Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826

HOBART TAS 7001

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**INFLIXIMAB**

**Authority required**

- Initial 1 (new patients)

Initial treatment of Crohn disease in a patient assessed by CDAI.

Initial PBS-subsidised treatment with infliximab by a gastroenterologist or a consultant physician as specified in the NOTE below, of a patient with severe refractory Crohn disease who satisfies the following criteria:

(a) has confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician as specified in the NOTE below; and

(b) has signed a patient acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and

(c) has failed to achieve an adequate response to prior systemic therapy including:

(i) a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period; and
ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

(ii) immunosuppressive therapy including:
— azathioprine at a dose of at least 2 mg per kg daily for 3 or more months; or
— 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months; or
— methotrexate at a dose of at least 15 mg weekly for 3 or more months.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of the accepted toxicities including severity can be found on the Medicare Australia website (www.medicareaustralia.gov.au).

The following initiation criterion indicates failure to achieve an adequate response and must be demonstrated in all patients at the time of the application:
(a) have a severity of disease activity which results in a Crohn Disease Activity Index (CDAI) Score greater than or equal to 300 as assessed.

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

The most recent CDAI assessment must be no more than 1 month old at the time of application.

Applications for authorisation must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) the completed current Crohn Disease Activity Index (CDAI) calculation sheet including the date of assessment of the patient's condition; and;
(ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and
(iii) the signed patient acknowledgement.

A maximum quantity and number of repeats to provide for an initial course of infliximab consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of infliximab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

A CDAI assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment

**Authority required**

Initial 2

Change or re-commencement of treatment of Crohn disease in a patient assessed by CDAI.

Initial PBS-subsidised treatment with infliximab by a gastroenterologist or a consultant physician as specified in the NOTE below of a patient who:
(a) has a documented history of severe refractory Crohn disease; and
(b) in this treatment cycle, has received prior PBS-subsidised treatment with infliximab or adalimumab for this condition; and
(c) has not failed PBS-subsidised therapy with infliximab for this condition more than once in the current treatment cycle.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of TNF-alfa antagonist therapy within the timeframes specified in the relevant restriction.

Where the most recent course of PBS-subsidised TNF-alfa antagonist treatment was approved under an initial treatment restriction, the patient must have been assessed for response to that course following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

If the response assessment to the previous course of TNF-alfa antagonist treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of TNF-alfa antagonist.

Authority applications must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) the completed current Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the 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 maintained 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 short gut syndrome or an ostomy patient.

Initial PBS-subsidised treatment with infliximab by a gastroenterologist, or consultant physician as specified in the NOTE below of a patient who satisfies the following criteria:

(a) has confirmed Crohn disease defined by standard clinical, endoscopic and/or imaging features, including histological evidence with the diagnosis confirmed by a gastroenterologist or consultant physician as specified in the NOTE below; and
(b) has diagnostic imaging or surgical evidence of short gut syndrome or has an ileostomy or colostomy; and
(c) has evidence of intestinal inflammation; and
(d) has signed a patient acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and
(e) has failed to achieve an adequate response to prior systemic drug therapy including:
(i) a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period; and
(ii) immunosuppressive therapy including:
— azathioprine at a dose of at least 2 mg per kg daily for 3 or more months; or
— 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months; or
— methotrexate at a dose of at least 15 mg weekly for 3 or more months.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.
If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of the accepted toxicities including severity can be found on the Medicare Australia website (www.medicareaustralia.gov.au).

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the application:

(a) have evidence of intestinal inflammation, including:
   (i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; AND/OR
   (ii) faeces: higher than normal lactoferrin or calprotectin level; AND/OR
   (iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery;
   AND/OR
(b) be assessed clinically as being in a high faecal output state;
   AND/OR
(c) be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of infliximab.

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the continuing treatment restriction. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and
(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
   (i) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and
   (ii) reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; and
   (iii) date of the most recent clinical assessment; and
   (iv) the signed patient acknowledgement.

All assessments, pathology tests and diagnostic imaging studies must be made within 1 month of the date of application.

A maximum quantity and number of repeats to provide for an initial course of infliximab consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of infliximab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

The assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment.

**Authority required**

**Initial 2**

Change or re-commencement of treatment of Crohn disease in a patient with short gut syndrome, an ostomy patient or a patient with extensive small intestine disease.

Initial PBS-subsidised treatment with infliximab by a gastroenterologist or a consultant physician as specified in the NOTE below of a patient who:

(a) has a documented history of severe refractory Crohn disease; and
(b) in this treatment cycle, has received prior PBS-subsidised treatment with infliximab or adalimumab for this condition; and
(c) has not failed PBS-subsidised therapy with infliximab for this condition more than once in the current treatment cycle.

**NOTE:** Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of TNF-alfa antagonist therapy within the timeframes specified in the relevant restriction.

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 alpha 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 6 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

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HSD (Public)
(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).

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the application:

(a) have severity of disease activity which results in a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220;

AND/OR

(b) have evidence of active intestinal inflammation, including:

(i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; AND/OR

(ii) faeces: higher than normal lactoferrin or calprotectin level; AND/OR

(iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery;

AND/OR

(c) be assessed clinically as being in a high faecal output state;

AND/OR

(d) be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of infliximab.

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the continuing treatment restriction. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and

(ii) (1) reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; or

(2) the completed current Crohn Disease Activity Index (CDAI) calculation sheet including the dates of assessment of the patient's condition, if relevant; and

(iii) date of the most recent clinical assessment; and

(iv) the signed patient acknowledgement.

All assessments, pathology tests and diagnostic imaging studies must be made within 1 month of the date of application.

A maximum quantity and number of repeats to provide for an initial course of infliximab consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of infliximab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

The assessment of the patient’s response to 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, 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 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 consulting 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;

(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) 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 date of clinical assessment(s); and

(iv) 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

TREATMENT OF ADULT PATIENTS WITH SEVERE REFRACTORY CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab and infliximab for adult patients with severe refractory Crohn disease. Where the term 'tumour necrosis factor (TNF) alpha antagonist' appears in the following NOTES and restrictions, it refers to adalimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 2 TNF-alpha antagonists at any 1 time.

From 1 August 2008, under the PBS, all patients will be able to commence a treatment cycle where they may trial each PBS-subsidised TNF-alpha antagonist without having to experience a disease flare when swapping to the alternate agent.

Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a TNF-alpha antagonist while they continue to show a response to therapy.

A patient who received PBS-subsidised TNF-alpha antagonist treatment prior to 1 August 2008 is considered to be in their first cycle as of 1 August 2008.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised TNF-alpha antagonist more than twice.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised TNF-alpha antagonist therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised TNF-alpha antagonist treatment in the most recent cycle to the date of the first application for initial treatment with a TNF-alpha antagonist under the new treatment cycle.

A patient who has failed fewer than 3 trials of TNF-alpha antagonists in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of TNF-alpha antagonists in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised TNF-alpha antagonist therapy after 1 August 2008.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised TNF-alpha antagonist treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) TNF-alpha antagonist therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to re-commence treatment with a specific TNF-alpha antagonist following a break in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks of therapy for 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-alpha antagonist.

For second and subsequent courses of PBS-subsidised TNF-alpha 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-alpha 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-alpha 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-alpha 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-alpha antagonist.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised TNF-alpha antagonist is approved, a patient may swap if eligible to the alternate TNF-alpha 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 course 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 100 mg injection, 1 x 100 mg vial**

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**INFLIXIMAB**

**Authority required**

Severe psoriatic arthritis

Treatment Phase: Initial treatment – Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more)

**Clinical criteria:**

Patient must have severe active psoriatic arthritis, **AND**

Patient must have received no prior PBS-subsidised treatment with a biological agent for this condition; **OR**

Patient must have received no PBS-subsidised treatment with a biological agent for at least 5 years if they have previously received PBS-subsidised treatment with a biological agent for this condition, **AND**

Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months, **AND**

Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; **OR**

Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months, **AND**

Patient must not receive more than 22 weeks of treatment under this restriction.

**Population criteria:**

Patient must be an adult.

**Treatment criteria:**

Must be treated by a rheumatologist; **OR**

Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

For the purposes of this restriction ‘biological agent’ means adalimumab, certolizumab pegol, etanercept, golimumab or infliximab.

Where treatment with methotrexate, sulfasalazine or leflunomide is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

Where intolerance to treatment with methotrexate, sulfasalazine or leflunomide developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.
The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

- an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; and

either

(a) an active joint count of at least 20 active (swollen and tender) joints; or
(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and
(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form; and
(3) a signed patient acknowledgement.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats may be authorised.

Note

Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 3 months treatment with methotrexate and 3 months treatment with sulfasalazine or leflunomide can be found on the Department of Human Services website (www.humanservices.gov.au)

**Authority required**

Severe psoriatic arthritis

**Treatment Phase: Initial treatment – Initial 2 (change or recommencement of treatment)**

**Clinical criteria:**

Patient must have a documented history of severe active psoriatic arthritis, AND

Patient must have received prior PBS subsidised treatment with a biological agent for this condition in this Treatment Cycle, AND

Patient must not have already failed, or ceased to respond to, PBS subsidised treatment with 3 biological agents within this Treatment Cycle, AND

Patient must not have failed, or ceased to respond to, PBS subsidised treatment with this drug during the current Treatment Cycle, AND

Patient must not receive more than 22 weeks of treatment under this restriction.

**Population criteria:**

Patient must be an adult.

**Treatment criteria:**

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab or infliximab.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and
(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats may be authorised.

Applications for a patient who has previously received PBS subsidised treatment with this drug within this Treatment Cycle and who wishes to recommence therapy with this drug within this same Cycle, must be accompanied by evidence of a response to the patient's most recent course of PBS subsidised treatment with this drug.

Where the most recent course of PBS subsidised treatment was approved under either of the initial treatment restrictions (i.e. for patients with no prior PBS subsidised biological therapy or, under this restriction, for patients who have received previous PBS subsidised biological therapy), the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must have been submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS subsidised treatment with this drug was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment submitted no later than 4 weeks from the date that course was ceased.

Where a response assessment was not submitted within these timeframes, the patient will be deemed to have failed to respond to treatment.

An adequate response to treatment is defined as:

- an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).
(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

**Note**
The assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted to the Department of Human Services no later than 4 weeks from the cessation of the treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

**Authority required**
Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more) or Initial 2 (change or recommencement of treatment) - balance of supply

**Clinical criteria:**
Patient must have received insufficient therapy with this drug under the Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more) restriction to complete 22 weeks treatment; OR
Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement of treatment) restriction to complete 22 weeks treatment, **AND**
The treatment must provide no more than the balance of up to 22 weeks treatment available under the above restrictions.

**Treatment criteria:**
Must be treated by a rheumatologist; OR
Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Note**
Authority approval for sufficient therapy to complete a maximum of 22 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 22 weeks of treatment should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826

HOBART TAS 7001

**Authority required**
Severe psoriatic arthritis

Treatment Phase: Continuing treatment

**Clinical criteria:**
Patient must have a documented history of severe active psoriatic arthritis, **AND**
Patient must have received this drug as their most recent course of PBS-subsidised treatment with a biological agent for this condition in the current Treatment Cycle, **AND**
Patient must demonstrate, at the time of application, an adequate response to treatment with this drug, **AND**
Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

**Population criteria:**
Patient must be an adult.

**Treatment criteria:**
Must be treated by a rheumatologist; OR
Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab or infliximab.

An adequate response to treatment is defined as:
an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and
either of the following:
(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:
(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).
The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications.

All applications for continuing treatment with this drug must include a measurement of response to the most recent course of PBS-subsidised therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with the initial treatment course.

Where a response assessment is not submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.
The authority application must be made in writing and must include:

(1) a completed authority prescription form; and
(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats may be authorised.

**Note**

Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle. Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (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 SEVERE ACTIVE PSORIATIC ARTHRITIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, certolizumab pegol, etanercept, golimumab and infliximab for adult patients with severe active psoriatic arthritis.

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological agents at any 1 time. Where the term ‘biological agents’ appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab and infliximab only.

Patients receiving PBS-subsidised treatment for psoriatic arthritis are able to commence a ‘Biological Treatment Cycle’ (Cycle), where they may trial biological agents without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

Following demonstration of response to initial treatment, these biological agents are available under the PBS for continuing treatment as set out in the continuing treatment restriction for each agent. Once patients have either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological therapy before they are eligible to commence another Cycle [further details are under ‘(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy’ below].

The duration of the break in therapy will be measured from the date the last approval for PBS-subsidised treatment was granted in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Cycle. Within the same Cycle, patients are not allowed to fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for any biological agent, they must change to an alternate agent which they have not previously failed, if they wish to continue PBS-subsidised biological treatment. Patient groups for whom a break in PBS-subsidised therapy of less than 5 years has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle. There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

**How to prescribe biological agents for the treatment of severe active psoriatic arthritis.**

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); and
(ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; and
(iii) patients wish to re-commence treatment with a specific biological agent following a break in PBS-subsidised therapy with that specific agent (Initial 2).

All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept and golimumab, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), and 22 weeks of therapy for infliximab. It is recommended that patients be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological agent supply. Patients must be assessed for response to any course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

Grandfather patients - certolizumab pegol only.

For patients who commenced treatment with certolizumab pegol for psoriatic arthritis prior to 1 April 2015, applications for initial PBS-subsidised treatment as continuing therapy may be made under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with any biological agent prior to PBS listing of that agent.

Schedule of Pharmaceutical Benefits 937
Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment for all agents. Approval will be based on the criteria included in the relevant restriction.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological agent, patients may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. Patients are eligible to receive continuing biological treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

Patients must be assessed for response to a course of continuing therapy, and the assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

(3) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate biological agent without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements.

Patients may swap to an alternate biological agent at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological agent at the time of the application or not.

Within a Treatment Cycle patients may alternate between therapy with any biological agent of their choice (1 at a time) providing:

(i) they have not received PBS-subsidised treatment with that particular biological agent previously; or

(ii) they have demonstrated an adequate response to that particular biological agent if they have previously trialled it on the PBS; and

(iii) they have not previously failed to respond to treatment 3 times in this Treatment Cycle.

To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the biological agent the patient is ceasing.

(4) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the indices of disease severity submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment application is submitted within a treatment Cycle and these revised baseline measurements will be used to assess response.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

Patients who wish to trial a second or subsequent treatment Cycle following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment with respect to both the indices of disease severity. Patients must have received treatment with methotrexate and sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured.

**Authority required**

Severe psoriatic arthritis

Treatment Phase: Continuing treatment - balance of supply

**Clinical criteria:**

Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, **AND**

The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Treatment criteria:**

Must be treated by a rheumatologist; **OR**

Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Note**

Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001
### Schedule of Pharmaceutical Benefits

**Interleukin inhibitors**

<table>
<thead>
<tr>
<th>Drug Name and Manufacturer</th>
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<tr>
<td><strong>Remicade [JC]</strong></td>
</tr>
<tr>
<td><strong>Kineret [FK]</strong></td>
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</table>

### ANAKINRA

**Authority required (STREAMLINED)**

**4920**

**Moderate to severe cryopyrin associated periodic syndromes (CAPS)**

**Treatment criteria:**

- Must be treated by a rheumatologist or in consultation with a rheumatologist.
- A diagnosis of CAPS must be documented in the patient's medical records.

**Note**

This drug is not PBS-subsidised for conditions other than CAPS.

### ANAKINRA

**anakinra 100 mg/0.67 mL injection, 28 x 0.67 mL syringes**

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</tbody>
</table>

### TOCILIZUMAB

**Authority required**

Initial 1 (new and recommencing patients after a break of more than 12 months)

- Initial treatment by a rheumatologist, or under the supervision of a paediatric rheumatology treatment centre, of a patient under 18 years who:
  - (a) has been diagnosed with systemic juvenile idiopathic arthritis; AND
  - (b) has polyarticular course disease and either:
    - (i) failure to achieve an adequate response to the following treatment regimen (see (1) below for definition of failure to achieve an adequate response):
      - oral or parenteral methotrexate at a dose of at least 15 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids for a minimum of 3 months; or
    - (ii) severe intolerance of, or toxicity due to, methotrexate (see (2) below for definition of severe intolerance and toxicity); OR
  - (c) has refractory systemic symptoms, demonstrated by:
    - an inability to decrease and maintain the dose of prednisolone (or equivalent) below 0.5 mg per kg per day following a minimum of 2 months of therapy; AND
  - (d) has not received PBS-subsidised treatment with tocilizumab for this condition in the previous 12 months.

(1) The following criteria indicate failure to achieve an adequate response to prior methotrexate therapy and must be demonstrated in all patients at the time of the initial application:

- (a) in a patient with polyarticular course disease:
  - (i) an active joint count of at least 20 active (swollen and tender) joints; OR
  - (ii) at least 4 active joints from the following list:
    - elbow, wrist, knee and/or ankle (assessed as swollen and tender); AND/OR
    - shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

- (b) in a patient with refractory systemic symptoms:
  - (i) an active joint count of at least 2 active joints; AND
  - (ii) persistent fever greater than 38 degrees Celsius for at least 5 out of 14 consecutive days; AND/OR
  - (iii) a C-reactive protein (CRP) level and platelet count above the upper limits of normal (ULN).

(2) Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant NSAIDs on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.

Toxicity to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonia, or serious sepsis.

If treatment with methotrexate alone or in combination with other treatments is contraindicated according to the relevant TGA-approved Product Information, please provide details at time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of this toxicity at the time of application.

The baseline measurements of joint count, fever and/or CRP level and platelet count must be performed preferably whilst on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be provided for all subsequent continuing treatment applications.

The authority application must be made in writing and must include:

1. completed authority prescription form(s); and
2. a completed Systemic Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
   - (i) the date of assessment of severe active systemic juvenile idiopathic arthritis;
(ii) details of prior treatment including dose and duration of treatment;
(iii) pathology reports detailing CRP and platelet count where appropriate; and
(3) a signed patient or authorised guardian acknowledgement form.

The most recent systemic juvenile idiopathic arthritis assessment must be no more than 1 month old at the time of application.

A maximum of 16 weeks of treatment will be authorised under this restriction.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for two infusions (one month supply). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

Where fewer than 3 repeats are requested at the time of initial application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Assessment of a patient's response to an initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 4 weeks from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab.

If a patient fails to respond to 2 courses of treatment in a treatment cycle they will not be eligible to receive further PBS-subsidised tocilizumab therapy in that treatment cycle. A patient may re-trial tocilizumab after a minimum of 12 months have elapsed between the date the last PBS-subsidised treatment was stopped and the date of the first application under a new treatment cycle

**Authority required**

**Initial 2 (retrial or recommencement of treatment after a break of less than 12 months)**

Initial PBS-subsidised treatment by a rheumatologist, or under the supervision of a paediatric rheumatology treatment centre, of a patient who:

(a) has a documented history of systemic juvenile idiopathic arthritis; AND
(b) has received PBS-subsidised treatment with tocilizumab for this condition in the previous 12 months; AND
(c) has not failed PBS-subsidised therapy with tocilizumab for this condition more than once in the current treatment cycle.

The authority application must be made in writing and must include:

(1) completed authority prescription form(s); and
(2) a completed Systemic Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) pathology reports detailing CRP and platelet count where appropriate; and

Applications for a patient who has received 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 (ˈgrandfather’ 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:
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 months 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.
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

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 one 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-alpha antagonists prior to 1 August 2010 please contact Medicare Australia on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction.

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.

(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.

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, 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.

Special Pricing Arrangements apply.

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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 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. 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.

**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).

**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**
Use of alternative DMARDs in children is dependent on approval by the Therapeutic Goods Administration as age restrictions may apply.
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

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.
**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 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; AND
Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR
Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if 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.

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tocilizumab 200 mg/10 mL injection, 1 x 10 mL vial

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<tr>
<th>Max.Qty Packs</th>
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<tr>
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<td>Actemra [RO]</td>
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**tocilizumab 400 mg/20 mL injection, 1 x 20 mL vial**

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**tocilizumab 80 mg/4 mL injection, 1 x 4 mL vial**

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**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
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826

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**HOBART TAS 7001**

 tocilizumab 200 mg/10 mL injection, 1 x 10 mL vial

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tocilizumab 400 mg/20 mL injection, 1 x 20 mL vial

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tocilizumab 80 mg/4 mL injection, 1 x 4 mL vial

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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 demonstrate 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.

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after break of less than 24 months)

Clinical criteria:

Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years,
AND
Patient must have received prior PBS-subsidised treatment with adalimumab, etanercept or tocilizumab for this condition in this treatment cycle, AND
Patient must not have failed PBS-subsidised therapy with tocilizumab for this condition in the current treatment cycle, AND
Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a rheumatologist; OR
Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.

The authority application must be made in writing and must include:
(1) completed authority prescription form(s); and
(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

Applications for a patient who has received PBS-subsidised treatment with tocilizumab in this treatment cycle and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient’s most recent course of PBS-subsidised tocilizumab treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised tocilizumab treatment was approved under either of the Initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised tocilizumab treatment was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab.

If a patient fails to respond to PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle.

An adequate response to treatment is defined as:

- an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

- AND either of the following:
  (a) an active joint count of fewer than 10 active (swollen and tender) joints; or
  (b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or
  (c) a reduction in the number of the following active joints, from at least 4, by at least 50%:
     (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
     (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

**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
Reply Paid 9826
GPO Box 9826

HOBART TAS 7001

**Authority required**

Severe active juvenile idiopathic arthritis

**Treatment Phase:** Continuing treatment

**Clinical criteria:**

Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years, AND

Patient must have demonstrated an adequate response to treatment with tocilizumab, AND

Patient must have received tocilizumab as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment in this treatment cycle, AND

Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

**Population criteria:**

Patient must be aged 18 years or older.

**Treatment criteria:**
Must be treated by a rheumatologist; OR
Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

For the purposes of this restriction ‘biological disease modifying anti-rheumatic drug’ and ‘bDMARD’ mean adalimumab, etanercept or tocilizumab.

An adequate response to treatment is defined as:

- an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline.

AND either of the following:

- (a) an active joint count of fewer than 10 active (swollen and tender) joints; or
- (b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or
- (c) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
- (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

1. completed authority prescription form(s); and
2. a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 5 repeats will be authorised.

All applications for continuing treatment with tocilizumab must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with tocilizumab, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab.

If a patient fails to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle.

Note

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826

HOBART TAS 7001

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 has received prior PBS-subsidised therapy with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy. A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. A patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count and ESR/CRP) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.

(4) Re-commencement of treatment after a 24 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 24 months, must requalify for treatment under the Initial 1 treatment restriction.

**Authority required**
Severe active juvenile idiopathic arthritis

**Clinical criteria:**
Patient must have received insufficient tocilizumab therapy under the Continuing Treatment restriction to complete 24 weeks treatment, AND

The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Treatment criteria:**
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
TOCILIZUMAB

Authority required

Severe active rheumatoid arthritis

Clinical criteria:
Patient must have severe active rheumatoid arthritis, AND
Patient must have received no PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition in the previous 24 months, AND
Patient must not have failed previous PBS-subsidised treatment with tocilizumab for this condition, and have not already failed, or ceased to respond to, PBS-subsidised bDMARD treatment for this condition 5 times, AND
Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR
Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR
Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above, must include at least 3 months continuous treatment with each of at least 2 DMARDs, with one or more of the following DMARDs being used in place of the DMARDs which are contraindicated or not tolerated: (i) azathioprine at a dose of at least 1 mg/kg per day; and/or (ii) cyclosporin at a dose of at least 2 mg/kg/day; and/or (iii) sodium aurothiomalate at a dose of 50 mg weekly, AND
Patient must not receive more than 16 weeks of treatment under this restriction.

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

Treatment criteria:
Must be treated by a rheumatologist; OR
Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.
For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab or tocilizumab.
If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate.
The maximum tolerated dose of methotrexate must be documented in the application, if applicable.
The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.
The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.
If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application.
The authority application must be made in writing and must include:
(1) completed authority prescription form(s); and
(2) authority application.
(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form; and
(3) a signed patient acknowledgement.

At the time of the authority application, medical practitioners should request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 8 mg per kg. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

If a patient fails to demonstrate a response to treatment with tocilizumab under this restriction they will not be eligible to receive further PBS subsidised treatment with this drug for this condition.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

- an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either
  - (a) a total active joint count of at least 20 active (swollen and tender) joints; or
  - (b) at least 4 active joints from the following list of major joints:
    - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
    - (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Where the baseline joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP is provided with the initial application, the same marker will be used to determine response.

Note

The Department of Human Services website (www.humanservices.gov.au) has details of the toxicities, including severity, which will be accepted for the following purposes:

(a) exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose;
(b) substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial;
(c) exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or re-commencement of treatment after break of less than 24 months).

Clinical criteria:

Patient must have a documented history of severe active rheumatoid arthritis, AND

Patient must have received prior PBS subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition and are eligible to receive further bDMARD therapy, AND

Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab or tocilizumab.

The authority application must be made in writing and must include:

(a) completed authority prescription form(s); and

(b) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners should request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 8 mg per kg. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

Applications for a patient who has received PBS subsidised treatment with tocilizumab and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS subsidised tocilizumab treatment, within the timeframes specified below.

Where the most recent course of PBS subsidised tocilizumab treatment was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

The most recent course of PBS subsidised tocilizumab treatment was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab.

If a patient fails to demonstrate a response to a treatment with tocilizumab under this restriction they will not be eligible to receive further PBS subsidised treatment with this drug for this condition.
If a patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Note
Special Pricing Arrangements apply.

Authority required
Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months) or Initial 2 (change or recommencement of treatment after break of less than 24 months) – balance of supply.

Clinical criteria:
Patient must have received insufficient tocilizumab therapy under the Initial 1 (new patient or patient recommencing treatment after break of more than 24 months) restriction to complete 16 weeks treatment; OR

Patient must have received insufficient tocilizumab therapy under the Initial 2 (change or recommencement of treatment after break of less than 24 months) restriction to complete 16 weeks treatment, AND

The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Treatment criteria:
Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Note
Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:

Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826

HOBART TAS 7001

Authority required
Severe active rheumatoid arthritis

Treatment Phase: Continuing treatment.

Clinical criteria:
Patient must have a documented history of severe active rheumatoid arthritis, AND

Patient must have demonstrated an adequate response to treatment with tocilizumab, AND

Patient must have received tocilizumab as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment, AND

Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

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

Treatment criteria:
Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab or tocilizumab.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).
Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) completed authority prescription form(s); and
(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners should request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 8 mg per kg. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 5 repeats will be authorised.

All applications for continuing treatment with tocilizumab must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with tocilizumab, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab.

If a patient fails to demonstrate a response to treatment with tocilizumab under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826

HOBART TAS 7001

TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alpha antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab) and the T-cell co-stimulation modulator (abatacept).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any one time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alpha antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:

- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alpha antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent 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 no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab and tocilizumab, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing
regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current course treatment. Abatacept patients:

Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:

A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction. Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept patients:

Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation. In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements. To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major
joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

**Authority required**

Severe active rheumatoid arthritis

**Clinical criteria:**

- Patient must have received insufficient tocilizumab therapy under the 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**

tocilizumab 200 mg/10 mL injection, 1 x 10 mL vial

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tocilizumab 400 mg/20 mL injection, 1 x 20 mL vial

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**Calcineurin inhibitors**

### CYCLOSPORIN

**Caution**

Careful monitoring of patients is mandatory.

**Authority required (STREAMLINED)**

3333

For use by organ or tissue transplant recipients

cyclosporin 50 mg/mL injection, 10 x 1 mL ampoules

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### CYCLOSPORIN

**Caution**

Careful monitoring of patients is mandatory.

**Authority required (STREAMLINED)**

3328

Management of rejection in patients following organ or tissue transplantation, under the supervision and direction of a transplant unit. Management includes initiation, stabilisation and review of therapy as required

**Authority required (STREAMLINED)**

3329

Management (which includes initiation, stabilisation and review of therapy) by dermatologists or clinical immunologists of patients with severe atopic dermatitis for whom other systemic therapies are ineffective or inappropriate

**Authority required (STREAMLINED)**

3330
Management (which includes initiation, stabilisation and review of therapy) by dermatologists of patients with severe psoriasis for whom other systemic therapies are ineffective or inappropriate and in whom the disease has caused significant interference with quality of life

**Authority required (STREAMLINED)**

3331

Management (which includes initiation, stabilisation and review of therapy) by nephrologists of patients with nephrotic syndrome in patients in whom steroids and cytostatic drugs have failed or are not tolerated or are considered inappropriate and in whom renal function is unimpaired

**Authority required (STREAMLINED)**

3332

Management (which includes initiation, stabilisation and review of therapy) by rheumatologists or clinical immunologists of patients with severe active rheumatoid arthritis for whom classical slow-acting anti-rheumatic agents (including methotrexate) are ineffective or inappropriate

cyclosporin 10 mg capsule, 60

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cyclosporin 100 mg capsule, 30

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cyclosporin 100 mg/mL oral liquid, 50 mL

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**TACROLIMUS**

**Caution**

Careful monitoring of patients is mandatory.

**Authority required (STREAMLINED)**

3328

Management of rejection in patients following organ or tissue transplantation, under the supervision and direction of a transplant unit. Management includes initiation, stabilisation and review of therapy as required

tacrolimus 1 mg capsule, 100

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tacrolimus 1 mg capsule: modified release, 60 capsules

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tacrolimus 500 microgram capsule, 100

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LENALIDOMIDE

**Authority required**

Myelodysplastic syndrome

**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 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

Patient must have received PBS

Patient must have a deletion 5q cytogenetic abnormality with or without additional cytogenetic abnormalities, **AND**

**Clinical criteria:**

**Treatment Phase: Initial treatment**

**Myelodysplastic syndrome**

**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 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

**Authority required**

Myelodysplastic syndrome

**Clinical criteria:**

Patient must be classified as Low risk or Intermediate-1 according to the International Prognostic Scoring System (IPSS), **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
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).

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

**Authority required**

Multiple myeloma

**Treatment Phase: Continuing PBS-subsidised treatment**

**Clinical criteria:**

Patient must have previously received an authority prescription for lenalidomide, **AND**

Patient must not have progressive disease, **AND**

The treatment must be as monotherapy; **OR**

The treatment must be in combination with dexamethasone.

Progressive disease is defined as at least 1 of the following:
(a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or
(b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or
(c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase of the difference between involved free light chain and uninvolved free light chain; or
(d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or
(e) an increase in the size or number of lytic bone lesions (not including compression fractures); or
(f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or
(g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Patients receiving lenalidomide under the PBS listing must be registered in the i-access risk management program.

**Note**

Authority applications for continuing treatment may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authority to prescribe should be forwarded to:
### RITUXIMAB

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (patient recommencing treatment after a break of more than 24 months)

**Clinical criteria:**

Patient must have severe active rheumatoid arthritis, **AND**

Patient must have failed to respond to at least 1 PBS-subsidised tumour necrosis factor (TNF) alfa antagonist, **AND**

Patient must have received no PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition in the previous 24 months, **AND**

Patient must not have failed previous PBS-subsidised treatment with rituximab for this condition, and have not already failed, or ceased to respond to, PBS-subsidised bDMARD treatment for this condition 5 times, **AND**

Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR

Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR

Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above, must include at least 3 months continuous treatment with each of at least 2 DMARDs, with one or more of the following DMARDs being used in place of the DMARDs which are contraindicated or not tolerated: (i) azathioprine at a dose of at least 1 mg/kg per day; and/or (ii) cyclosporin at a dose of at least 2 mg/kg/day; and/or (iii) sodium aurothiomalate at a dose of 50 mg weekly, **AND**

Patient must not receive more than 2 infusions of rituximab under this restriction, **AND**

The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

**Population criteria:**

Patient must be aged 18 years or older.

**Treatment criteria:**

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

For the purposes of this restriction ‘TNF’ alfa antagonist means adalimumab, certolizumab pegol, etanercept, golimumab and infliximab.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab or tocilizumab

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.
The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application.

The authority application must be made in writing and must include:

1. completed authority prescription form(s); and
2. a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form; and
3. a signed patient acknowledgement.

Assessment of a patient's response to an initial course of treatment must be made at least 12 weeks after the first infusion so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services within 4 weeks of the date it was conducted. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with rituximab.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. If a patient who fails to demonstrate a response to treatment with rituximab under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

A patient who fails to demonstrate a response to rituximab treatment and who qualifies to trial an alternate bDMARD according to the interchangeability arrangements for bDMARDs for the treatment of severe rheumatoid arthritis, may do so without having to have a 22 week treatment-free period.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

- an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either
  (a) a total active joint count of at least 20 active (swollen and tender) joints; or
  (b) at least 4 active joints from the following list of major joints:
    (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
    (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).
  The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Where the baseline joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP is provided with the initial application, the same marker will be used to determine response.

**Note**

The Department of Human Services website (www.humanservices.gov.au) has details of the toxicities, including severity, which will be accepted for the following purposes:

- (a) exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose;
- (b) substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial;
- (c) exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy.

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or re-commencement of treatment after break of less than 24 months).

**Clinical criteria:**

- Patient must have a documented history of severe active rheumatoid arthritis, **AND**
- Patient must have failed to respond to at least 1 PBS-subsidised tumour necrosis factor (TNF) alfa antagonist, **AND**
- Patient must have received prior PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition and are eligible to receive further bDMARD therapy, **AND**
- Patient must not receive more than 2 infusions of rituximab under this restriction, **AND**

The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

For the purposes of this restriction ‘TNF’ alfa antagonist means adalimumab, certolizumab pegol, etanercept, golimumab and infliximab.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab or tocilizumab.
The authority application must be made in writing and must include:
(a) completed authority prescription form(s); and
(b) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

Applications for a patient who has received PBS-subsidised treatment with rituximab and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised rituximab treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised rituximab treatment was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response at least 12 weeks after the first infusion. This assessment must be submitted no later than 4 weeks from the date of the assessment.

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent provided they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The demonstration of response must be submitted within 4 weeks of assessment.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with rituximab.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction.

If a patient fails to demonstrate a response to treatment with rituximab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

If a patient fails to demonstrate a response to a treatment with rituximab and who qualify to trial an alternate bDMARD according to the interchangeability arrangements for bDMARDs for the treatment of severe rheumatoid arthritis, may do so without having to have a 22 week treatment-free period.

An adequate response to treatment is defined as:
an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;
AND either of the following:
(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:
   (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
   (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Continuing treatment

Clinical criteria:
Patient must have a documented history of severe active rheumatoid arthritis, AND
Patient must have demonstrated an adequate response to treatment with this drug, AND
Patient must have received this drug as the most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition, AND
Patient must not receive more than 2 infusions of rituximab under this restriction, AND
The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

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

Treatment criteria:
Must be treated by a rheumatologist; OR
Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab or tocilizumab.

The authority application must be made in writing and must include:
(a) completed authority prescription form(s); and
(b) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent provided they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The demonstration of response must be submitted within 4 weeks of assessment.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with rituximab.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction.

If a patient fails to demonstrate a response to treatment with rituximab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

An adequate response to treatment is defined as:
an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;
AND either of the following:
(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:
   (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
Schedule of Pharmaceutical Benefits

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Note

Special Pricing Arrangements apply.

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826

HOBART TAS 7001

TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alpha antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab) and the T-cell co-stimulation modulator (abatacept).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alpha antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:

- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy;
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alpha antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD was stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under ‘Swapping therapy’ below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab and tocilizumab, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current course.

Abatacept patients:

Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient’s weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.
Rituximab patients:
A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients:
A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept patients:
Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is approved, and the Department of Human Services will assess response according to these revised baseline measurements. To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

**rituximab 500 mg/50 mL injection, 1 x 50 mL vial**

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**THALIDOMIDE**

**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.

**Authority required (STREAMLINED)**
3342
Multiple myeloma

Note
Patients receiving thalidomide under the PBS listing must be registered in the i-access risk management program.

thalidomide 100 mg capsule, 28
9667T

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thalidomide 50 mg capsule, 28
9566L

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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

baclofen 10 mg/5 mL injection: intrathecal, 1 x 5 mL ampoule
5617P

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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

ibandronic acid 6 mg/6 mL injection, 1 x 6 mL vial
5750P

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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.

pamidronate disodium 15 mg/5 mL injection, 1 x 5 mL vial
5667G

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pamidronate disodium 60 mg/10 mL injection, 1 x 10 mL vial

5669J

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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.

pamidronate disodium 30 mg injection [2 x 30 mg vials] (&) inert substance diluent [2 x 10 mL ampoules], 1 pack

5702D

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- **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.

pamidronate disodium 90 mg injection [1 x 90 mg vial] (&) inert substance diluent [1 x 10 mL ampoule], 1 pack

5703E

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- **Note**
  
  Pharmaceutical benefits that have the form disodium pamidronate powder for I.V. infusion 180 mg (after reconstitution) and pharmaceutical benefits that have the form disodium pamidronate concentrated injection 180 mg are equivalent for the purposes of substitution.

- **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.

Zoledronic acid 4 mg/5 mL injection, 1 x 5 mL vial

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**NERVOUS SYSTEM**

**ANTI-PARKINSON DRUGS**

**DOPAMINERGIC AGENTS**

*Dopa and dopa derivatives*

**LEVODOPA + CARBIDOPA ANHYDROUS**

*Authority required (STREAMLINED)*

**3704**

Management of advanced Parkinson disease in a patient with severe disabling motor fluctuations not adequately controlled by oral therapy.

Treatment must be commenced in a hospital-based movement disorder clinic

*Note*

Patients should have adequate cognitive function to manage administration with a portable continuous infusion pump.

A positive clinical response to Duodopa administered via a temporary nasoduodenal tube should be confirmed before a permanent percutaneous endoscopic gastrostomy (PEG) tube is inserted.

Levodopa 20 mg/mL + carbidopa monohydrate 5 mg/mL gel: intestinal, 7 x 100 mL bags

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**Dopamine agonists**

**APOMORPHINE**

*Authority required (STREAMLINED)*

**4833**

Parkinson disease

*Clinical criteria:*

Patient must have experienced severely disabling motor fluctuations which have not responded to other therapy.

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

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Apomorphine hydrochloride 20 mg/2 mL injection, 5 x 2 mL ampoules

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Apomorphine hydrochloride 50 mg/10 mL injection: subcutaneous infusion, 5 x 10 mL syringes

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Apomorphine hydrochloride 50 mg/5 mL injection, 5 x 5 mL ampoules

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**PSYCHOLEPTICS**

**ANTIPSYCHOTICS**

*Diazepines, oxazepines, thiazepines and oxepines*

**CLOZAPINE**

*Authority required (STREAMLINED)*

**4411**

Schizophrenia

*Clinical criteria:*

Patient must be non-responsive to other neuroleptic agents; OR

Patient must be intolerant of other neuroleptic agents.

A medical practitioner should request a quantity sufficient for up to one month’s supply. Up to 5 repeats will be authorised.

*Note*
Patients receiving clozapine under the PBS listing must be registered in a clozapine patient monitoring program; Novartis Clozaril Patient Monitoring System (eCPMS) or Clopineconnect.

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### RESPIRATORY SYSTEM

#### DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES

**OTHER SYSTEMIC DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES**

*Other systemic drugs for obstructive airway diseases*

**OMALIZUMAB**

**Authority required**

Uncontrolled severe allergic asthma

**Treatment Phase: Initial treatment**

**Clinical criteria:**

- Patient must be under the care of the same physician for at least 12 months, **AND**
- Patient must have 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 the following standard clinical features: (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**
- Patient must have a duration of asthma of at least 1 year, **AND**
- Patient must have forced expiratory volume (FEV1) less than or equal to 80% predicted, documented on 3 or more occasions in the previous 12 months, **AND**
- Patient must have past or current evidence of atopy, documented by skin prick testing or RAST, **AND**
- Patient must have total serum human immunoglobulin E greater than or equal to 76 IU/mL, **AND**
- Patient must have 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**
- Patient must have failed to achieve adequate control with optimised asthma therapy, despite formal assessment of and adherence to correct inhaler technique, which has been documented, **AND**
- Patient must not receive more than 28 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 12 years or older.

**Treatment criteria:**

- Must be treated by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma.

- 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) treatment with oral corticosteroids, either daily oral corticosteroids for at least 6 weeks, OR a cumulative dose of oral corticosteroids of at least 500 mg prednisolone equivalent in the previous 12 months, 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. The initial IgE assessment must be no more than 12 months old at the time of 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 receiving optimised asthma therapy 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 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 22 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 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 within this timeframe, the patient will be deemed to have failed to respond to treatment with omalizumab.

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.

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.

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, 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 in the past 12 months while receiving optimised asthma therapy (date and treatment); and
(iii) the signed patient acknowledgement; and
(c) the IgE pathology report; and
(d) a completed Asthma Control Questionnaire (ACQ-5) calculation sheet including the date of assessment of the patient’s symptoms.

Note
The Department of Human Services website (www.humanservices.gov.au) has 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.

It is recommended that an application for continuing treatment is submitted at the time of the 22 to 26 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised omalizumab treatment.

Authority required
Uncontrolled severe allergic asthma
Treatment Phase: Initial treatment - balance of supply

Clinical criteria:
Patient must have received insufficient therapy with this drug under the Initial treatment restriction to complete 28 weeks treatment, AND
The treatment must provide no more than the balance of up to 28 weeks treatment available under the above restriction.

Treatment criteria:
Must be treated by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma.

Note
Authority approval for sufficient therapy to complete a maximum of 28 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 28 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
Uncontrolled severe allergic asthma
Treatment Phase: Continuing treatment

Clinical criteria:
Patient must have a documented history of severe allergic asthma, **AND**
Patient must have demonstrated or sustained an adequate response to treatment with this drug, **AND**
Patient must not receive more than 24 weeks of treatment under this restriction.

**Treatment criteria:**
Must be treated by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma.

An adequate response to omalizumab treatment is defined as:
(a) a reduction in the Asthma Control Questionnaire (ACQ) 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.

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 18 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. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted 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 within this timeframe, the patient will be deemed to have failed to respond to treatment with omalizumab.

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.

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.

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 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.

**Note**
If the same physician cannot assess the patient please call the Department of Human Services on 1800 700 270.

For copies of the ACQ please contact Novartis Medical Information on 1800 671 203 or medinfo.phauno@novartis.com

It is recommended that an application for continuing treatment is submitted at the time of the 18 to 22 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised omalizumab treatment.

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

Prescribing information (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 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) 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.
   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.

2. **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 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 the Department of Human Services 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) 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.

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.humanservices.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 (1 800 645 130).

**Authority required**

Uncontrolled severe allergic asthma
Treatment Phase: Continuing treatment - balance of supply

**Clinical criteria:**
Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, AND
The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Treatment criteria:**
Must be treated by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma.

**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

SPECIAL PRICING ARRANGEMENTS apply.

**omalizumab 150 mg/mL injection, 1 x 1 mL syringe**

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**omalizumab 75 mg/0.5 mL injection, 1 x 0.5 mL syringe**

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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 suppurative lung disease (cough and sputum most days of the week, or greater than 3 respiratory tract infections of more than 2 weeks’ duration in any 12 months, or objective evidence of obstructive airways disease).

**Population criteria:**
Patient must be 5 years of age or older.
Patient must be assessed at a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis. The prescribing of dornase alfa therapy under the HSD program is limited to such physicians. If attendance at such a unit is not possible because of geographical isolation, management (including prescribing) may be by a specialist physician or paediatrician in consultation with such a unit.

The measurement of lung function is to be conducted by independent (other than the treating doctor) experienced personnel at an established lung function testing laboratory, unless this is not possible because of geographical isolation.

Prior to dornase alfa therapy, a baseline measurement of forced expiratory volume in 1 second (FEV1) must be undertaken during a stable period of the disease.

Initial therapy is limited to 3 months treatment with dornase alfa at a dose of 2.5 mg daily.

FEV1 measurement (single test under conditions as above) and a global assessment of the patient involving the patient, the patient's family (in the case of paediatric patients), the treating physician(s) and an additional independent member of the cystic fibrosis treatment team must be undertaken and documented following 3 months of initial therapy.

To be eligible for continued PBS-subsidised treatment with dornase alfa following 3 months of initial treatment:

(1) the patient must demonstrate no deterioration in FEV1 compared to baseline; AND
(2) the patient or the patient's family (in the case of paediatric patients) must report improvement in the patient's airway clearance; AND
(3) the treating physician(s) must report a benefit in the clinical status of the patient.

Further reassessments involving the patient, the patient's family (in the case of paediatric patients), the treating physician(s) and an additional independent member of the cystic fibrosis treatment team must be undertaken and documented at six-monthly intervals to establish that all agree that dornase alfa treatment is continuing to produce worthwhile benefits.

Dornase alfa therapy should cease if there is not general agreement of benefit as there is always the possibility of harm from unnecessary use.

Other aspects of treatment, such as physiotherapy, must be continued.

Where there is documented evidence that a patient already receiving dornase alfa therapy would have met the criteria for subsidy, then the patient is eligible to continue treatment under the HSD program. Where such evidence is not available, patients will need to satisfy the initiation and continuation criteria as for new patients. (Four weeks is considered a suitable wash-out period.)

**Authority required (STREAMLINED)***

**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 conventional therapy.

**Population criteria:**

Patient must be less than 5 years of age.

Patient must be assessed at a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis. The prescribing of dornase alfa therapy under the HSD program is limited to such physicians. If attendance at such a unit is not possible because of geographical isolation, management (including prescribing) may be by a specialist physician or paediatrician in consultation with such a unit.

Following an initial 6 months therapy, a comprehensive assessment must be undertaken and documented involving the patient, the patient's family, the treating physician and an additional independent member of the cystic fibrosis treatment team to establish agreement that dornase alfa treatment is continuing to produce worthwhile benefit. Treatment with dornase alfa should cease if there is not agreement of benefit, as there is always the possibility of harm from unnecessary use. Further reassessments must be undertaken and documented at six-monthly intervals.

**Authority required (STREAMLINED)***

**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.
It is highly desirable that all patients be included in the national cystic fibrosis patient database.

**MANNITOL**

**Authority required (STREAMLINED)**

**4299**

**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 (STREAMLINED)**

**4293**

**Cystic fibrosis**

**Clinical criteria:**

Patient must have initiated treatment with mannitol prior to 1 August 2012, **AND**

Patient must have undergone a comprehensive assessment involving the patient's family, the treating physician and an additional independent member of the cystic fibrosis team, which documents agreement that mannitol treatment is continuing to produce a worthwhile benefit.

**Population criteria:**

Patient must be 6 years of age or older.
Further reassessments are to be undertaken and documented every 6 months. Treatment with mannitol should cease if there is not agreement of benefit as there is always the possibility of harm from unnecessary use.

**Note**
Mannitol is not PBS-subsidised for use in combination with PBS-subsidised dornase alfa.
It is highly desirable that all patients be included in the national cystic fibrosis patient database.

**MANNITOL**
Pack containing 280 capsules containing powder for inhalation 40 mg and 2 inhalers, 1
2015C

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**OTHER RESPIRATORY SYSTEM PRODUCTS**

**IVACAFTOR**

**Authority required**

Cystic fibrosis

**Treatment Phase:** Initial treatment – New patients

**Clinical criteria:**

- Patient must be assessed through a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis. If attendance at such a unit is not possible because of geographical isolation, management (including prescribing) may be in consultation with such a unit, **AND**
- Patient must have G551D mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene on at least 1 allele; **OR**
- Patient must have other gating (class III) mutation in the CFTR gene on at least 1 allele, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with standard therapy for this condition.

**Population criteria:**

- Patient must be 6 years of age or older.
- Patients receiving PBS-subsidised ivacaftor must be registered in the Australian Cystic Fibrosis Database Registry.
- Treatment must not be given to a patient who has an acute upper or lower respiratory infection, pulmonary exacerbation, or changes in therapy (including antibiotics) for pulmonary disease in the last 4 weeks prior to commencing this drug.
- Dosage of ivacaftor must not exceed the dose of 150 mg twice a week, if the patient is concomitantly receiving one of the following moderate CYP3A4 inhibitors: boceprevir, clarithromycin, conivaptan, indinavir, ltraconazole, ketoconazole, lopinavir/ritonavir, mibefradil, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole.
- Where a patient is concomitantly receiving a strong CYP3A4 inhibitor, a single supply of 56 tablets of ivacaftor will last for 28 weeks.
- Dosage of ivacaftor must not exceed the dose of 150 mg daily, if the patient is concomitantly receiving one of the following moderate CYP3A4 inhibitors: amprenavir, aperpitan, atazanavir, darunavir/ritonavir, diltiazem, erythromycin, fluconazole, fosamprenavir, imatinib, verapamil.
- Where a patient is concomitantly receiving a moderate CYP3A4 inhibitor, a single supply of 56 tablets of ivacaftor will last for 8 weeks.
- Ivacaftor is not PBS-subsidised for this condition as a sole therapy.
- Ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers:
  - Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John's wort
  - Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, rifampin
- Weak CYP3A4 inducers: armodafinil, echinacea, pioglitazone, prednisone, rufinamide.

The authority application must be in writing and must include:

1. a completed authority prescription form; and
2. a completed Cystic Fibrosis Ivacaftor Authority Application Supporting Information Form; and
3. a signed patient acknowledgement; or an acknowledgement signed by a parent or authorised guardian, if applicable; and
4. a copy of the pathology report detailing the molecular testing for G551D mutation or other gating (class III) mutation on the CFTR gene; and
5. the result of a FEV1 measurement performed within a month prior to the date of application. Note: FEV1, must be measured in an accredited pulmonary function laboratory, with documented no acute infective exacerbation at the time FEV1 is measured; and
6. evidence that the patient has either chronic sinopulmonary disease or gastrointestinal and nutritional abnormalities; and
7. a copy of a current medication history, including any CYP3A4 inhibitors and/or CYP3A4 inducers; and
8. a copy of a sweat chloride result; and
9. height and weight measurements at the time of application; and
10. a baseline measurement of the number of days of CF-related hospitalisation (including hospital-in-the-home) in the previous 12 months.

**Authority required**

Cystic fibrosis
Treatment Phase: Continuing treatment

Clinical criteria:
Patient must be assessed through a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis. If attendance at such a unit is not possible because of geographical isolation, management (including prescribing) may be in consultation with such a unit, AND
Patient must have received PBS-subsidised initial therapy with ivacaftor, given concomitantly with standard therapy, for this condition, AND
Patient must not receive more than 24 weeks of treatment under this restriction, AND
The treatment must be given concomitantly with standard therapy for this condition.

Population criteria:
Patient must be 6 years of age or older.
Patients receiving PBS-subsidised ivacaftor must be registered in the Australian Cystic Fibrosis Database Registry.
Treatment must not be given to a patient who has an acute upper or lower respiratory infection, pulmonary exacerbation, or changes in therapy (including antibiotics) for pulmonary disease in the last 4 weeks prior to commencing this drug.
Patients who have an acute infective exacerbation at the time of assessment for continuing therapy may receive an additional one month's supply in order to enable the assessment to be repeated following resolution of the exacerbation.
Dosage of ivacaftor must not exceed the dose of 150 mg twice a week, if the patient is concomitantly receiving one of the following strong CYP3A4 drugs inhibitors: boceprevir, clarithromycin, conivaptan, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, mibebradil, nefazodone, neflinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole.
Where a patient is concomitantly receiving a strong CYP3A4 inhibitor, a single supply of 56 tablets of ivacaftor will last for 28 weeks.
Dosage of ivacaftor must not exceed the dose of 150 mg daily, if the patient is concomitantly receiving one of the following moderate CYP3A4 inhibitors: amsaprenavir, aprepitant, atazanavir, darunavir/ritonavir, diltiazem, erythromycin, fluconazole, fosamprenavir, imatinib, verapamil.
Where a patient is concomitantly receiving a moderate CYP3A4 inhibitor, a single supply of 56 tablets of ivacaftor will last for 8 weeks.
Ivacaftor is not PBS-subsidised for this condition as a sole therapy.
Ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers:
Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John's wort
Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, nafcillin
Weak CYP3A4 inducers: armodafinil, echinacea, pioglitazone, prednisone, rufinamide.
The authority application must be in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Cystic Fibrosis Ivacaftor Authority Continuing Application Supporting Information Form; and
(3) the result of a FEV1 measurement performed within one month prior to the date of application. Note: FEV1 must be measured in an accredited pulmonary function laboratory, with documented no acute infective exacerbation at the time FEV1 is measured; and
(4) a copy of a current medication history, including any CYP3A4 inhibitors and/or CYP3A4 inducers; and
(5) a recent sweat chloride result; and
(6) height and weight measurements at the time of application; and
(7) a measurement of number of days of CF-related hospitalisation (including hospital in the home) in the previous 6 months.

Authority required
Cystic fibrosis
Treatment Phase: Initial treatment - Grandfather patients
Clinical criteria:
Patient must be assessed through a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis. If attendance at such a unit is not possible because of geographical isolation, management (including prescribing) may be in consultation with such a unit, AND
Patient must have G551D mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene on at least 1 allele; OR
Patient must have other gating (class III) mutation in the CFTR gene on at least 1 allele, AND
Patient must have received treatment with ivacaftor for this condition prior to 1 December 2014, AND
Patient must have received treatment with ivacaftor within the last 6 months at the time of application, AND
Patient must not receive more than 24 weeks of treatment under this restriction, AND
The treatment must be given concomitantly with standard therapy for this condition.

Population criteria:
Patient must be 6 years of age or older.
Patients receiving PBS-subsidised ivacaftor must be registered in the Australian Cystic Fibrosis Database Registry.
Treatment must not be given to a patient who has an acute upper or lower respiratory infection, pulmonary exacerbation, or changes in therapy (including antibiotics) for pulmonary disease in the last 4 weeks prior to commencing this drug.
Dosage of ivacaftor must not exceed the dose of 150 mg twice a week, if the patient is concomitantly receiving one of the following strong CYP3A4 drugs inhibitors: boceprevir, clarithromycin, conivaptan, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, mibebradil, nefazodone, neflinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole.
Where a patient is concomitantly receiving a strong CYP3A4 inhibitor, a single supply of 56 tablets of ivacaftor will last for 28 weeks.
Dosage of ivacaftor must not exceed the dose of 150 mg daily, if the patient is concomitantly receiving one of the following moderate CYP3A4 inhibitors: amprenavir, aprepitant, atazanavir, darunavir/ritonavir, diltiazem, erythromycin, fluconazole, fosamprenavir, imatinib, verapamil.

Where a patient is concomitantly receiving a moderate CYP3A4 inhibitor, a single supply of 56 tablets of ivacaftor will last for 8 weeks.

Ivacaftor is not PBS-subsidised for this condition as a sole therapy.

Ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers:

**Strong CYP3A4 inducers**: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John's wort
**Moderate CYP3A4 inducers**: bosentan, efavirenz, etravirine, modafinil, nafcillin
**Weak CYP3A4 inducers**: armodafinil, echinacea, pioglitazone, prednisone, rufinamide.

The authority application must be in writing and must include:

1. A completed authority prescription form; and
2. A completed Cystic Fibrosis Ivacaftor Application Supporting Information Form; and
3. A signed patient acknowledgement; or an acknowledgement signed by a parent or authorised guardian, if applicable; and
4. A copy of the pathology report detailing the molecular testing for G551D mutation or other gating (class III) mutation on the CFTR gene performed prior to commencing treatment with ivacaftor; and
5. The result of a FEV1 measurement performed prior to commencing treatment with ivacaftor; and
6. The result of a FEV1 measurement performed within a month prior to date of application. Note: FEV1, must be measured in an accredited pulmonary function laboratory, with documented no acute infective exacerbation at the time FEV1 is measured; and
7. Evidence that the patient had either chronic sinopulmonary disease or gastrointestinal and nutritional abnormalities prior to commencing treatment with ivacaftor for this condition; and
8. A copy of a current medication history, including any CYP3A4 inhibitors and/or CYP3A4 inducers; and
9. A copy of sweat chloride result performed prior to commencing treatment with ivacaftor for this condition; and
10. A recent sweat chloride result prior to commencing PBS-subsidised ivacaftor; and
11. Height and weight measurements at the time of application; and
12. Height and weight measurements performed immediately prior to commencement of ivacaftor; and
13. A baseline measurement of number of days of CF-related hospitalisation (including hospital-in-the home) in the 12 months prior to commencement of ivacaftor; and
14. A measurement of the number of days of CF-related hospitalisation (including hospital-in-the home) in the 6 months prior to the date of application; and
15. Dates of prior ivacaftor therapy.

**Note**

Special Pricing Arrangements apply.

No increase in the maximum number of repeats may 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**

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### VARIOUS

### ALL OTHER THERAPEUTIC PRODUCTS

### Iron chelating agents

### DEFERASIROX

**Authority required (STREAMLINED)**

**3828**

Chronic iron overload in patients with disorders of erythropoiesis

**Note**

Special Pricing Arrangements apply.
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#### DEFERIPRONE

**Authority required (STREAMLINED)**

3338
Iron overload in patients with thalassaemia major who are unable to take desferrioxamine therapy

**Authority required (STREAMLINED)**

3339
Iron overload in patients with thalassaemia major in whom desferrioxamine therapy has proven ineffective

### deferiprone 100 mg/mL oral liquid, 250 mL

<table>
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<th>Code</th>
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<th>No. of Rpts</th>
<th>Premium $</th>
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<tr>
<td>5658T</td>
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<td>*1126.40</td>
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### deferiprone 500 mg tablet, 100

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#### DESFERRIOXAMINE

**Authority required (STREAMLINED)**

3340
Disorders of erythropoiesis associated with treatment-related chronic iron overload

### desferrioxamine mesylate 2 g injection, 1 x 2 g vial

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### desferrioxamine mesylate 500 mg injection, 10 x 500 mg vials

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**Drugs for treatment of hyperkalemia and hyperphosphataemia**

#### LANTHANUM

**Authority required (STREAMLINED)**

4832
Hyperphosphataemia

**Clinical criteria:**
- The condition must not be adequately controlled by calcium, **AND**
- Patient must have a serum phosphate of greater than 1.6 mmol per L at the commencement of therapy; **OR**
- The condition must be where a serum calcium times phosphate product is greater than 4 at the commencement of therapy, **AND**
- The treatment must not be used in combination with any other phosphate binding agents.

**Treatment criteria:**
- Patient must be undergoing dialysis for chronic kidney disease.

### LANTHANUM Tablet, chewable, 1000 mg (as carbonate hydrate), 90

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<thead>
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<th>Code</th>
<th>Max Qty Packs</th>
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<td>*890.02</td>
<td>Fosrenol [ZI]</td>
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### LANTHANUM Tablet, chewable, 500 mg (as carbonate hydrate), 90

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<tr>
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### LANTHANUM Tablet, chewable, 750 mg (as carbonate hydrate), 90

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#### SEVELAMER

**Authority required (STREAMLINED)**

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<tbody>
<tr>
<td>Treatment Phase: Initiation and stabilisation</td>
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</tbody>
</table>

**Clinical criteria:**

- The condition must not be adequately controlled by calcium, **AND**
- Patient must have a serum phosphate of greater than 1.6 mmol per L at the commencement of therapy; **OR**
- The condition must be where a serum calcium times phosphate product is greater than 4 at the commencement of therapy, **AND**
- The treatment must not be used in combination with any other phosphate binding agents.

**Treatment criteria:**

- Patient must be undergoing dialysis for chronic kidney disease.

#### SUCROFERRIC OXYHYDROXIDE

**Authority required (STREAMLINED)**

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<tbody>
<tr>
<td>Treatment Phase: Initiation and stabilisation</td>
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</table>

**Clinical criteria:**

- The condition must not be adequately controlled by calcium, **AND**
- Patient must have a serum phosphate of greater than 1.6 mmol per L at the commencement of therapy; **OR**
- The condition must be where a serum calcium times phosphate product is greater than 4 at the commencement of therapy, **AND**
- The treatment must not be used in combination with any other phosphate binding agents.

**Treatment criteria:**

- Patient must be undergoing dialysis for chronic kidney disease.

#### iron (as sucroferric oxyhydroxide) 500 mg tablet: chewable, 90

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<td>*753.46 Velphoro [FN]</td>
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Botulinum Toxin Program

MUSCULO-SKELETAL SYSTEM.................................................................................................................984

MUSCLE RELAXANTS ................................................................................................................................. 984
MUSCLE RELAXANTS, PERIPHERALLY ACTING AGENTS .................................................................984
Other muscle relaxants, peripherally acting agents ................................................................. 984
MUSCULO-SKELETAL SYSTEM

MUSCLE RELAXANTS

MUSCLE RELAXANTS, PERIPHERALLY ACTING AGENTS

Other muscle relaxants, peripherally acting agents

BOTULINUM TOXIN TYPE A

Restricted benefit
Botulinum toxin type A

Restricted benefit
Blepharospasm or hemifacial spasm

Population criteria:
Patient must be aged 12 years or older.

Restricted benefit
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.

Restricted benefit
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.

Restricted benefit
Spasmodic torticollis

Clinical criteria:
The treatment must be as monotherapy; OR
The treatment must be as adjunctive therapy to current standard care.

Restricted benefit
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.

Restricted benefit
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
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.

Restricted benefit
Moderate to severe spasticity of the upper limb following a stroke

Clinical criteria:
The treatment must be used as second line therapy when standard management has failed (e.g. physiotherapy and/or oral spasticity agents) or as an adjunct to physical therapy.

Population criteria:
Patient must be an adult.
Moderate to severe spasticity is defined as MAS greater than or equal to 3 using modified Ashworth scale.
Maximum number of treatments to be authorised is 4 (total Xeomin®, Botox® and Dysport®) per upper limb per lifetime.
Treatment should not be initiated until 3 months post-stroke in patients who do not have established severe contracture.
Treatment should be discontinued if the patient does not respond (decrease of MAS greater than 1 in at least one joint) after two treatments.
The date of the stroke must be provided.
Contraindications to treatment include established severe contracture and known sensitivity to botulinum toxin.
**Restricted benefit**
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.

**Restricted benefit**
Urinary incontinence

**Clinical criteria:**
The condition must be due to neurogenic detrusor overactivity, as demonstrated by urodynamic study, **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.

**Restricted benefit**
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.

**Restricted benefit**
Urinary incontinence

**Clinical criteria:**
The condition must be due to idiopathic overactive bladder, **AND**
The condition must have been inadequately controlled by therapy involving at least two alternative anti-cholinergic agents, **AND**
Patient must experience at least 14 episodes of urinary incontinence per week prior to commencement of treatment with botulinum toxin, **AND**
The treatment must not continue if the patient does not achieve a 50% or greater reduction from baseline in urinary incontinence episodes 6-12 weeks after the first treatment, **AND**
Patient must be willing and able to self-catheterise.

**Population criteria:**
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.
The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent. Special Pricing Arrangements apply.

<table>
<thead>
<tr>
<th>botulinum toxin type A 100 units injection, 1 x 100 units vial</th>
</tr>
</thead>
<tbody>
<tr>
<td>6103F</td>
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<tr>
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</table>

**CLOSTRIDIUM BOTULINUM TYPE A TOXIN-HAEMAGGLUTININ COMPLEX**

**Restricted benefit**
Moderate to severe spasticity of the upper limb following a stroke

**Clinical criteria:**
The treatment must be used as second line therapy when standard management has failed (e.g. physiotherapy and/or oral spasticity agents) or as an adjunct to physical therapy.

**Population criteria:**
Patient must be an adult.
Moderate to severe spasticity is defined as MAS greater than or equal to 3 using modified Ashworth scale.
Maximum number of treatments to be authorised is 4 (total Xeomin®, Botox® and Dysport®) per upper limb per lifetime. Treatment should not be initiated until 3 months post-stroke in patients who do not have established severe contracture. Treatment should be discontinued if the patient does not respond (decrease of MAS greater than 1 in at least one joint) after two treatments.

Contraindications to treatment include established severe contracture and known sensitivity to botulinum toxin.

**Restricted benefit**

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.

**Restricted benefit**

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 clostridium botulinum type A toxin-haemagglutinin complex as a paediatric patient.

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

**Restricted benefit**

Spasmodic torticollis

**Clinical criteria:**
The treatment must be as monotherapy; OR
The treatment must be as adjunctive therapy to current standard care.

**Restricted benefit**

Blepharospasm or hemifacial spasm

**Population criteria:**
Patient must be an adult.

**Note**
The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent. Arrangements to prescribe this item should be made by medical practitioners with the Department of Human Services, contact telephone number 1800 700 270.

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<table>
<thead>
<tr>
<th>clostridium botulinum type A toxin-haemagglutinin complex 500 units injection, 1 x 500 units vial</th>
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<td>Max Qty Packs</td>
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</tbody>
</table>

**INCOBOTULINUMTOXINA**

**Restricted benefit**

Spasmodic torticollis

**Clinical criteria:**
The treatment must be as monotherapy; OR
The treatment must be as adjunctive therapy to current standard care.

**Restricted benefit**

Blepharospasm

**Population criteria:**
Patient must be an adult.

**Restricted benefit**

Moderate to severe spasticity of the upper limb following a stroke

**Clinical criteria:**
The treatment must be used as second line therapy when standard management has failed (e.g. physiotherapy and/or oral spasticity agents) or as an adjunct to physical therapy.

**Population criteria:**
Patient must be an adult.

Moderate to severe spasticity is defined as MAS greater than or equal to 3 using modified Ashworth scale.

Maximum number of treatments to be authorised is 4 (total Xeomin®, Botox® and Dysport®) per upper limb per lifetime. Treatment should not be initiated until 3 months post-stroke in patients who do not have established severe contracture.
Treatment should be discontinued if the patient does not respond (decrease of MAS greater than 1 in at least one joint) after two treatments.
The date of the stroke must be provided.
Contraindications to treatment include established severe contracture and known sensitivity to botulinum neurotoxin.

**Note**
Arrangements to prescribe this item should be made by medical practitioners with the Department of Human Services, contact telephone number 1800 700 270.
The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent.

**incobotulinumtoxinA 100 mouse LD50 units injection, 1 x 100 mouse LD50 units vial**

<table>
<thead>
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<th>Max Qty Packs</th>
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<tr>
<td>1</td>
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Growth Hormone Program

SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS.........990

PITUITARY AND HYPOTHALAMIC HORMONES AND ANALOGUES.......................... 990
ANTERIOR PITUITARY LOBE HORMONES AND ANALOGUES............................. 990
Somatropin and somatropin agonists......................................................... 990
**SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS**

**PITUITARY AND HYPOTHALAMIC HORMONES AND ANALOGUES**

**ANTERIOR PITUITARY LOBE HORMONES AND ANALOGUES**

**Somatropin and somatropin agonists**

**SOMATROPIN**

*Restricted benefit*

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

**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

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<thead>
<tr>
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**SOMATROPIN** (Recombinant human growth hormone) Powder for injection 12 mg (36 i.u.) with diluent in pre-filled pen (with preservative), 1

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**SOMATROPIN** (Recombinant human growth hormone) Powder for injection 5 mg (15 i.u.) with diluent in pre-filled pen (with preservative), 1

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somatropin 1.8 international units (600 microgram) injection [7 x 600 microgram syringes] (&) inert substance diluent [7 x 0.25 mL syringes], 1 pack

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somatropin 12 international units (4 mg) injection [1 x 4 mg vial] (&) inert substance diluent [1 vial], 1 pack

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somatropin 15 international units (5 mg/1.5 mL) injection, 1 x 1.5 mL cartridge

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<th>Brand Name and Manufacturer</th>
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<td>Saizen [SG]</td>
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somatropin 4.2 international units (1.4 mg) injection [7 x 1.4 mg syringes] (&) inert substance diluent [7 x 0.25 mL syringes], 1 pack

<table>
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<th>Max.Qty Packs</th>
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<tr>
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somatropin 4.8 international units (1.6 mg) injection [7 x 1.6 mg syringes] (&) inert substance diluent [7 x 0.25 mL syringes], 1 pack

<table>
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<tr>
<td>1</td>
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somatropin 45 international units (15 mg/1.5 mL) injection, 1 x 1.5 mL cartridge

<table>
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<tbody>
<tr>
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somatropin 5.4 international units (1.8 mg) injection [7 x 1.8 mg syringes] (&) inert substance diluent [7 x 0.25 mL syringes], 1 pack

<table>
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<th>Brand Name and Manufacturer</th>
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<tr>
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</table>

somatropin 6 international units (2 mg) injection [7 x 2 mg syringes] (&) inert substance diluent [7 x 0.25 mL syringes], 1 pack

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
<th>Price ex manufacturer $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>693.00</td>
<td>Genotropin MiniQuick [PF]</td>
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</table>

somatropin 60 international units (20 mg/2.5 mL) injection, 1 x 2.5 mL cartridge

<table>
<thead>
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</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>990.00</td>
<td>Saizen [SG]</td>
</tr>
</tbody>
</table>

somatropin 72 international units (24 mg) injection [1 x 24 mg cartridge] (&) inert substance diluent [1 x 3.15 mL syringe], 1 pack

<table>
<thead>
<tr>
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<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>1188.00</td>
<td>Humatrope [LY]</td>
</tr>
</tbody>
</table>

**SOMATROPIN**

**Restricted benefit**

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
Special Pricing Arrangements apply.
<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>Price ex manufacturer $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>315.50</td>
<td>Norditropin FlexPro [NO]</td>
</tr>
<tr>
<td>1</td>
<td>631.00</td>
<td>Norditropin FlexPro [NO]</td>
</tr>
<tr>
<td>1</td>
<td>946.50</td>
<td>Norditropin FlexPro [NO]</td>
</tr>
</tbody>
</table>

**somatropin 15 international units (5 mg/1.5 mL) injection, 1 x 1.5 mL cartridge**

**somatropin 30 international units (10 mg/1.5 mL) injection, 1 x 1.5 mL cartridge**

**somatropin 45 international units (15 mg/1.5 mL) injection, 1 x 1.5 mL cartridge**
## IVF Treatment Program

### GENITO URINARY SYSTEM AND SEX HORMONES

<table>
<thead>
<tr>
<th>Category</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM</td>
<td>996</td>
</tr>
<tr>
<td>PROGESTOGENS</td>
<td>996</td>
</tr>
<tr>
<td>Pregnen (4) derivatives</td>
<td>996</td>
</tr>
<tr>
<td>GONADOTROPINS AND OTHER OVULATION STIMULANTS</td>
<td>996</td>
</tr>
<tr>
<td>Gonadotropins</td>
<td>996</td>
</tr>
</tbody>
</table>

### SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS

<table>
<thead>
<tr>
<th>Category</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>PITUITARY AND HYPOTHALAMIC HORMONES AND ANALOGUES</td>
<td>998</td>
</tr>
<tr>
<td>HYPOTHALAMIC HORMONES</td>
<td>998</td>
</tr>
<tr>
<td>Gonadotropin-releasing hormones</td>
<td>998</td>
</tr>
<tr>
<td>Anti-gonadotropin-releasing hormones</td>
<td>999</td>
</tr>
</tbody>
</table>
PROGESTERONE

Restricted benefit
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.

<table>
<thead>
<tr>
<th>Item Description</th>
<th>Max.Qty</th>
<th>Price ex manufacturer</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>progesterone 100 mg pessary, 15</td>
<td>1</td>
<td>50.40</td>
<td>Oripro [ON]</td>
</tr>
<tr>
<td>progesterone 100 mg pessary, 21</td>
<td>1</td>
<td>49.39</td>
<td>Endometrin [FP]</td>
</tr>
<tr>
<td>progesterone 200 mg pessary, 15</td>
<td>1</td>
<td>55.60</td>
<td>Oripro [ON]</td>
</tr>
</tbody>
</table>

GONADOTROPINS AND OTHER OVULATION STIMULANTS

Gonadotropins

CHORIOGNADOTROPIN ALFA

Restricted benefit
Patients who are receiving medical treatment 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.

Special Pricing Arrangements apply.
GENITO URINARY SYSTEM AND SEX HORMONES

**Schedule of Pharmaceutical Benefits**

### Choriogonadotropin Alfa

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
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<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>54.80</td>
<td>Ovidrel [SG]</td>
</tr>
</tbody>
</table>

### CORIFOLLITROPIN ALFA

**Restricted benefit**

**Controlled ovarian stimulation**

#### Clinical criteria:

Patient must have an antral follicle count of 20 or less.

#### Treatment criteria:

Patient must be undergoing treatment as described in items 13200, 13201 or 13202 of the Health Insurance (General Medical Services Table) Regulations, **AND**

Patient must be undergoing a gonadotrophin releasing hormone antagonist cycle.

**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.

<table>
<thead>
<tr>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Elonva [MK]</td>
</tr>
<tr>
<td>Elonva [MK]</td>
</tr>
</tbody>
</table>

### FOLLITROPIN ALFA

**Restricted benefit**

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>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>Gonalf-f Pen [SG]</td>
</tr>
<tr>
<td>Gonalf-f Pen [SG]</td>
</tr>
<tr>
<td>Gonalf-f Pen [SG]</td>
</tr>
</tbody>
</table>

### FOLLITROPIN BETA

**Restricted benefit**

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>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Puregon 300 IU/0.36 mL [MK]</td>
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</tbody>
</table>
follitropin beta 600 international units/0.72 mL injection, 1 x 0.72 mL cartridge

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
<th>Price ex manufacturer $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>292.72</td>
<td>Puregon 600 IU/0.72 mL [MK]</td>
</tr>
</tbody>
</table>

follitropin beta 900 international units/1.08 mL injection, 1 x 1.08 mL cartridge

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
<th>Price ex manufacturer $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>435.15</td>
<td>Puregon 900 IU/1.08 mL [MK]</td>
</tr>
</tbody>
</table>

**GONADOTROPHIN CHORIONIC HUMAN**

Restricted benefit

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.

gonadotrophin chorionic human 1500 international units injection [3 x 1500 international units ampoules] (&) inert substance diluent [3 x 1 mL ampoules], 1 pack

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
<th>Price ex manufacturer $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>39.57</td>
<td>Pregnyl [MK]</td>
</tr>
</tbody>
</table>

gonadotrophin chorionic human 5000 international units injection [1 x 5000 international units ampoule] (&) inert substance diluent [1 x 1 mL ampoule], 1 pack

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
<th>Price ex manufacturer $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>11.49</td>
<td>Pregnyl [MK]</td>
</tr>
</tbody>
</table>

**GONADOTROPHIN-MENOPAUSAL HUMAN**

Restricted benefit

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.

gonadotrophin-menopausal human 1200 international units injection [1 x 1200 international units vial] (&) inert substance diluent [2 x 1 mL syringes], 1 pack

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
<th>Price ex manufacturer $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>531.18</td>
<td>Menopur 1200 [FP]</td>
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</table>

gonadotrophin-menopausal human 600 international units injection [1 x 600 international units vial] (&) inert substance diluent [1 x 1 mL syringe], 1 pack

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
<th>Price ex manufacturer $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>265.59</td>
<td>Menopur 600 [FP]</td>
</tr>
</tbody>
</table>

**SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS**

**PITUITARY AND HYPOTHALAMIC HORMONES AND ANALOGUES**

**HYPOTHALAMIC HORMONES**

Gonadotropin-releasing hormones

**NAFARELIN**

Restricted benefit

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.

nafarelin 200 microgram/actuation nasal spray, 60 actuations

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
<th>Price ex manufacturer $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>106.00</td>
<td>Synarel [PF]</td>
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</tbody>
</table>
Anti-gonadotropin-releasing hormones

- **CETRORELIX**
  
  **Restricted benefit**
  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.

  **cetrorelix 250 microgram injection [1 x 250 microgram vial] (&) inert substance diluent [1 x 1 mL syringe], 1 pack**
  
<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
<th>Price ex manufacturer $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>46.08</td>
<td>Cetrotide [SG]</td>
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</tbody>
</table>

- **GANIRELIX**
  
  **Restricted benefit**
  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.

  **ganirelix 250 microgram/0.5 mL injection, 1 x 0.5 mL syringe**
  
<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
<th>Price ex manufacturer $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>46.08</td>
<td>Orgalutran [MK]</td>
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</tbody>
</table>

  **ganirelix 250 microgram/0.5 mL injection, 5 x 0.5 mL syringes**
  
<table>
<thead>
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<tbody>
<tr>
<td>1</td>
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<td>Orgalutran [MK]</td>
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</table>
Opiate Dependence Treatment Program

NERVOUS SYSTEM

OTHER NERVOUS SYSTEM DRUGS

DRUGS USED IN ADDICTIVE DISORDERS

Drugs used in opioid dependence
**NERVOUS SYSTEM**

**OTHER NERVOUS SYSTEM DRUGS**

**DRUGS USED IN ADDICTIVE DISORDERS**

*Drugs used in opioid dependence*

### BUPRENORPHINE

**Restricted benefit**

Treatment of opiate dependence, including maintenance and detoxification (withdrawal), within a framework of medical, social and psychological treatment

**Note**

Treatment must be in accordance with the law of the relevant State or Territory.

**Shared Care Model:**

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

<table>
<thead>
<tr>
<th>Buprenorphine 2 mg tablet, 7</th>
<th>6308B</th>
<th>Max Qty Packs</th>
<th>Price ex manufacturer</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>10.50</td>
<td>Subutex [RC]</td>
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</table>

<table>
<thead>
<tr>
<th>Buprenorphine 400 microgram tablet, 7</th>
<th>6307Y</th>
<th>Max Qty Packs</th>
<th>Price ex manufacturer</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>6.16</td>
<td>Subutex [RC]</td>
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<table>
<thead>
<tr>
<th>Buprenorphine 8 mg tablet, 7</th>
<th>6309C</th>
<th>Max Qty Packs</th>
<th>Price ex manufacturer</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>30.10</td>
<td>Subutex [RC]</td>
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<td></td>
</tr>
</tbody>
</table>

### BUPRENORPHINE + NALOXONE

**Caution**

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.

**Restricted benefit**

Treatment of opiate dependence within a framework of medical, social and psychological treatment

**Note**

Treatment must be in accordance with the law of the relevant State or Territory.

**Shared Care Model:**

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

<table>
<thead>
<tr>
<th>Buprenorphine 2 mg + naloxone 500 microgram film: sublingual, 28 films</th>
<th>9749D</th>
<th>Max Qty Packs</th>
<th>Price ex manufacturer</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>46.20</td>
<td>Suboxone Film 2/0.5 [RC]</td>
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<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Buprenorphine 8 mg + naloxone 2 mg film: sublingual, 28 films</th>
<th>9750E</th>
<th>Max Qty Packs</th>
<th>Price ex manufacturer</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>132.44</td>
<td>Suboxone Film 8/2 [RC]</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### METHADONE

**Caution**

The risk of drug dependence is high.

**Restricted benefit**

Treatment of opiate dependence in accordance with the law of the relevant State or Territory

**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.
### methadone hydrochloride 5 mg/mL oral liquid, 1000 mL

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>Price ex manufacturer $</th>
<th>Brand Name and Manufacturer</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>33.20</td>
<td>&quot;Aspen Methadone Syrup [QA]&quot;</td>
<td>&quot;Biodone Forte [MW]&quot;</td>
</tr>
</tbody>
</table>

### methadone hydrochloride 5 mg/mL oral liquid, 200 mL

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>Price ex manufacturer $</th>
<th>Brand Name and Manufacturer</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>7.91</td>
<td>&quot;Aspen Methadone Syrup [QA]&quot;</td>
<td>&quot;Biodone Forte [MW]&quot;</td>
</tr>
</tbody>
</table>
Repatriation Pharmaceutical Benefits Scheme

BENEFICIARIES’ ENTITLEMENT CARDS AND ELIGIBILITY FOR REPATRIATION PHARMACEUTICAL BENEFITS

Gold card
This card is issued to those veterans of Australia’s defence force, their widows/widowers and dependants entitled to treatment for all medical conditions.

White card
A White Card is issued to Australian veterans or mariners under the Veterans’ Entitlements Act 1986 with:
- an accepted war or service-caused injury or disease;
- malignant cancer (neoplasia) whether war-caused or not;
- pulmonary tuberculosis whether war-caused or not;
- post-traumatic stress disorder whether war-caused or not; or
- anxiety and/or depression whether war-caused or not.

Orange card
Orange Repatriation pharmaceutical benefits cards are issued to Commonwealth and allied veterans and mariners who:
- have qualifying service from World War I or II and
- are aged 70 or over and
- have been resident in Australia for 10 years or more.

For more information go to the Department of Veterans’ Affairs website: http://www.dva.gov.au
RPBS Explanatory Notes

Introduction

The Australian Repatriation System

- The Australian Repatriation system is based primarily on the principle of compensation to veterans and eligible dependants for injury or death related to war service. In certain cases, treatment is also provided for accepted injuries or conditions that are not service-related or have occurred as a result of other than war service.
- Through the Veterans’ Entitlements Act 1986 the Department of Veterans’ Affairs provides programs of compensation, income support and treatment for eligible veterans and their dependants. One of the defined benefits for eligible veterans is the Repatriation Pharmaceutical Benefits Scheme. This range of medications and dressings is more comprehensive than is available through the Pharmaceutical Benefits Scheme.

RPBS prescribing provisions

- Unless otherwise stated, Repatriation Pharmaceutical Benefits Scheme (RPBS) prescriptions must conform with the requirements of Pharmaceutical Benefits Scheme (PBS) prescriptions, as detailed in Section 1 – Explanatory Notes in the Schedule of Pharmaceutical Benefits book. The prescriber shall ensure that a prescription contains the following details:
  - the category of benefit, i.e., RPBS, by placing a cross in the relevant box;
  - the patient’s full name and address;
  - the prescription date;
  - the DVA file number of the patient as evidence of entitlement;
  - in the case of authority prescriptions, the Authority approval number or the four digit streamlined authority code;
  - the item, form, strength, quantity and directions;
  - the number of repeats, if applicable;
  - indicate when brand substitution is not permitted; and
  - the name, signature, the prescriber number and address of the prescriber.

Prior Approval Arrangements

- The prior approval of the Department is required to prescribe the following:
  - ‘Authority required’ items (excluding ‘Authority required (STREAMLINED)’ items) listed in either the PBS or RPBS Schedule;
  - increased quantities and/or repeats of items listed in either the PBS or RPBS Schedule;
  - items listed under section 100 of the National Health Act 1953; and
  - other items not listed in either Schedule (non-Schedule items).
- The above items are to be prescribed on the common PBS/RPBS authority prescription form in accordance with the directions stated in the Explanatory Notes in the Schedule of Pharmaceutical Benefits. (See also information regarding dental prescribing and prescribing by optometrists under the RPBS in these Notes.)
- All Authority required prescriptions and requests for non-Schedule items must receive prior approval from the Department. This can be achieved by either:
  - using the Department’s national free call number 1800 552 580; or
  - by mailing the written authority prescription to the Veterans’ Affairs Pharmaceutical Advisory Centre (VAPAC) at the reply paid address shown at the end of these RPBS Explanatory Notes.

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

- Some requests for prior approval (including some non-Schedule items) need to be referred by VAPAC to the Repatriation Pharmaceutical Reference Committee for consideration. In such cases a VAPAC pharmacist will advise the prescriber to submit a request in writing that provides the following information:
  - A current clinical report on the patient’s condition (such as age, co-morbidities, renal, liver failure) and clinical reports including pathology, biochemistry, diagnostic and other investigations if appropriate.
  - Details of past and current therapy for the condition. Include details of PBS, RPBS and non-Schedule items utilised, and the results of those therapies.
  - Details of the proposed treatment regimen. Include intended dose and duration of treatment and objective measures of response.
  - When the proposed use of the item is outside the TGA-approved indications for use in Australia, provide copies of articles from peer reviewed publications supporting the proposed treatment.
  - Signed, informed patient consent where the item is to be used for a non-TGA-approved indication.
  - For items without Australian marketing approval, a copy of the TGA Special Access Scheme approval to prescribe the drug.
  - Requests for prior approval to prescribe a non-Schedule (PBS or RPBS) item that is of the same therapeutic class (ATC level 3) as an item that is listed on the Schedule, will not be approved unless unequivocal clinical evidence is presented to demonstrate that the requested item is essential for effective treatment of the nominated patient.
  - A pharmacist should not supply an item prescribed on an RPBS Authority Prescription Form unless the form has been approved and stamped by VAPAC, or has been endorsed by the prescriber with a telephone Authority approval number provided by VAPAC. Medicare Australia 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: Where possible the LDO shall prescribe in accordance with the provisions governing dental prescribing under the Pharmaceutical Benefits Scheme (PBS).
  - a Gold Repatriation Health Card – For All Conditions; or
  - a White Repatriation Health Card – For Specific Conditions; or
  - an Orange Repatriation Pharmaceutical Benefits Card.
- 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. Medicare Australia 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 Medicare Australia. 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".

**Contact the 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.
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)

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
- Hydrogel—Amorphous
- Hydrogel—Sheet

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

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:

Schedule of Pharmaceutical Benefits 1009
(A) Absorbing
- Hydroactive (Superficial Wound—Light Exudate)
- Hydrocolloid (Superficial Wound—Light/Moderate Exudate)
- Hydrocolloid (Cavity Wound)

(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 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 only been secured with Independence Australia on 1300 788 855. Please note that Coloplast are unable to guarantee ready supply or rebate for price differences on purchases outside this distributor.

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 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.

ORDERING SMITH & NEPHEW PRODUCTS
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 agreed pricing from distributors other than those aforementioned.
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ALIMENTARY TRACT AND METABOLISM

STOMATOLOGICAL PREPARATIONS

Antiinfectives and antiseptics for local oral treatment

CHLORHEXIDINE
chlorhexidine gluconate 0.2% (2 mg/mL) mouthwash, 250 mL

<table>
<thead>
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<th>No. of Rpts</th>
<th>Premium $</th>
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chlorhexidine gluconate 0.2% (2 mg/mL) mouthwash, 300 mL

<table>
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<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
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<td>15.62</td>
<td>6.10</td>
<td>Savacol Mouth and Throat Rinse [OM]</td>
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DRUGS FOR ACID RELATED DISORDERS

ANTACIDS
Calcium compounds

CALCIUM CARBONATE + GLYCINE

Note
For patients with chronic renal failure.
calcium carbonate 420 mg + glycine 180 mg tablet: chewable, 100

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>4055K</td>
<td>2</td>
<td>5</td>
<td>23.52</td>
<td>6.10</td>
<td>Titalac [MM]</td>
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ALUMINIUM HYDROXIDE WITH MAGNESIUM HYDROXIDE AND SIMETHICONE

ALUMINIUM HYDROXIDE with MAGNESIUM HYDROXIDE and SIMETHICONE Oral suspension 400 mg-400 mg - 30 mg per 5 mL, 500 mL, 1

<table>
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<tr>
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<tr>
<td>4118R</td>
<td>2</td>
<td>5</td>
<td>22.98</td>
<td>6.10</td>
<td>Mylanta Double Strength [JT]</td>
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ALUMINIUM HYDROXIDE with MAGNESIUM HYDROXIDE and SIMETHICONE Tablet 400 mg-400 mg-40 mg, 100

<table>
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<tr>
<td>4453J</td>
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<td>46.46</td>
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<td>Mylanta Double Strength [JT]</td>
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DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS

Synthetic anticholinergics, esters with tertiary amino group

MEBEVERINE
mebeverine hydrochloride 135 mg tablet, 90

<table>
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<tr>
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<tr>
<td>4328T</td>
<td>1</td>
<td></td>
<td>27.25</td>
<td>6.10</td>
<td>* Colese [AF]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>32.43</td>
<td>6.10</td>
<td>* Colofac [GO]</td>
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BELLADONNA AND DERIVATIVES, PLAIN
Belladonna alkaloids, semisynthetic, quaternary ammonium compounds

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

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<tr>
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<tr>
<td>4279F</td>
<td>1</td>
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<td>24.55</td>
<td>6.10</td>
<td>Buscopan [BY]</td>
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DRUGS FOR CONSTIPATION

Softeners, emollients
### DOCUSATE

docusate sodium 50 mg tablet, 100

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<th>No. of Rpts</th>
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<th>DPMQ $</th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>2</td>
<td>..</td>
<td>14.65</td>
<td>6.10</td>
<td>Coloxy 50 [FM]</td>
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### Contact laxatives

docusate sodium 50 mg + sennoside B 8 mg tablet, 100

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<th>DPMQ $</th>
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<tr>
<td>1</td>
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<td>14.75</td>
<td>6.10</td>
<td>Soflax [GN]</td>
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docusate sodium 50 mg + sennoside B 8 mg tablet, 90

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<tr>
<td>1</td>
<td>2</td>
<td>..</td>
<td>13.48</td>
<td>6.10</td>
<td>Pharmacy Action Laxative with Senna [GQ]</td>
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### DOCUSATE + SENNOSIDES

docusate sodium 50 mg + sennosides 11.27 mg tablet, 90

<table>
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<tbody>
<tr>
<td>1</td>
<td>2</td>
<td>..</td>
<td>13.52</td>
<td>6.10</td>
<td>* Chemists’ Own Laxative with Senna [AS]</td>
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### SENNOSIDE B

sennoside B 7.5 mg tablet, 100

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<td>..</td>
<td>12.94</td>
<td>6.10</td>
<td>* Senna-Gen [PP]</td>
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### Bulk-forming laxatives

ispaghula husk dry 3.5 g oral liquid: powder for, 30 x 3.5 g sachets

<table>
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<tbody>
<tr>
<td>‡1</td>
<td>1</td>
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<td>17.98</td>
<td>6.10</td>
<td>Fybogel [RC]</td>
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### PSYLLIUM HUSK POWDER

PSYLLIUM HYDROPHILIC MUCILLOID Oral powder (non-flavoured) 336 g, 1

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<tr>
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<th>No. of Rpts</th>
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<tbody>
<tr>
<td>‡1</td>
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<td>18.36</td>
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<td>Fibre Health Natural Granular [PP]</td>
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<td>22.01</td>
<td>6.10</td>
<td>Metamucil Orange Smooth [PY]</td>
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PSYLLIUM HYDROPHILIC MUCILLOID Oral powder (orange-flavoured, sugar-free) 283 g, 1

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<tr>
<td>‡1</td>
<td>1</td>
<td>..</td>
<td>22.01</td>
<td>6.10</td>
<td>Metamucil Orange Smooth [PY]</td>
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### RHAMNUS FRANGULA + STERCULIA

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

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<tr>
<td>‡1</td>
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<td>26.71</td>
<td>6.10</td>
<td>Normacol Plus [NE]</td>
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### Enemas

SORBITOL + CITRATE + LAURYL SULFOACETATE SODIUM
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

<table>
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<tbody>
<tr>
<td>‡1</td>
<td>..</td>
<td>..</td>
<td>12.44</td>
<td>6.10</td>
<td>Micolette [AE]</td>
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</table>
**GLYCEROL**

**Restricted benefit**
Short-term use when oral laxative therapy has failed or is inappropriate

**glycerol 2.8 g suppository, 12**

<table>
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<tr>
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<tbody>
<tr>
<td>4246L</td>
<td>3</td>
<td>..</td>
<td>*22.15</td>
<td>6.10</td>
<td>Petrus Pharmaceuticals Pty Ltd [PP]</td>
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</table>

**ANTIOBESITY PREPARATIONS, EXCL. DIET PRODUCTS**

**PERIPHERALLY ACTING ANTIOBESITY PRODUCTS**

**ORLISTAT**

**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.

**orlistat 120 mg capsule, 84**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
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<th>MRVSN $</th>
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<tbody>
<tr>
<td>4570M</td>
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<td>2</td>
<td>140.50</td>
<td>6.10</td>
<td>Xenical [RO]</td>
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</table>

**VITAMINS**

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

**Thiamine**

**thiamine hydrochloride 100 mg tablet, 100**

<table>
<thead>
<tr>
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<th>No. of Rpts</th>
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<th>DPMQ $</th>
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<tbody>
<tr>
<td>4043T</td>
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<td>2</td>
<td>10.45</td>
<td>6.10</td>
<td>Betavit [PP]</td>
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</table>

**VITAMIN B-COMPLEX, INCL. COMBINATIONS**

**Thiamine**

**cyano-co-b-lamin + f-erric pyrophosphate + lysine + pyridoxine + thiamine**
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

<table>
<thead>
<tr>
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<tr>
<td>4493L</td>
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<td>13.68</td>
<td>6.10</td>
<td>Accomin Adult Tonic [PF]</td>
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</table>
BLOOD AND BLOOD FORMING ORGANS

MINERAL SUPPLEMENTS

CALCIUM

Calcium

CALCIUM

Restricted benefit
Hyperphosphataemia in chronic renal failure

CALCIIUM Tablet (chewable) 500 mg (as carbonate), 60

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
<th>No. of Rpts</th>
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<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>4</td>
<td>1</td>
<td>..</td>
<td>*29.24</td>
<td>6.10</td>
<td>* Cal-500 [PP]</td>
<td>* Cal-Sup [IA]</td>
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CALCIUM Tablet 600 mg (as carbonate), 120

<table>
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<tr>
<td>2</td>
<td>1</td>
<td>..</td>
<td>*22.54</td>
<td>6.10</td>
<td></td>
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</tbody>
</table>

CALCIUM

Restricted benefit
Hypocalcaemia

Restricted benefit
Osteoporosis

Restricted benefit
Proven calcium malabsorption

CALCIIUM Tablet (chewable) 500 mg (as carbonate), 60

<table>
<thead>
<tr>
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<th>Premium $</th>
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<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>2</td>
<td>1</td>
<td>..</td>
<td>*18.00</td>
<td>6.10</td>
<td>* Cal-500 [PP]</td>
<td>* Cal-Sup [IA]</td>
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CALCIUM Tablet 600 mg (as carbonate), 120

<table>
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<tr>
<td>1</td>
<td>1</td>
<td>..</td>
<td>14.65</td>
<td>6.10</td>
<td></td>
</tr>
</tbody>
</table>

OTHER MINERAL SUPPLEMENTS

Magnesium

MAGNESIUM ASPARTATE DIHYDRATE

Restricted benefit
Patients with documented hypomagnesaemia

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

<table>
<thead>
<tr>
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<tr>
<td>1</td>
<td>..</td>
<td>..</td>
<td>14.04</td>
<td>6.10</td>
<td>Mag-Sup [PP]</td>
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<td>..</td>
<td>..</td>
<td>14.73</td>
<td>6.10</td>
<td>Magmin [BB]</td>
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BLOOD AND BLOOD FORMING ORGANS

ANTITHROMBOTIC AGENTS

Platelet aggregation inhibitors excl. heparin

ASPIRIN

aspirin 100 mg tablet, 90

<table>
<thead>
<tr>
<th>Max.Qty Packs</th>
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<tr>
<td>1</td>
<td>1</td>
<td>..</td>
<td>16.01</td>
<td>6.10</td>
<td>Cardiprin 100 [RC]</td>
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</table>

ASPIRIN

Note
The enteric coated preparations are for patients with a significant risk of gastrointestinal bleeding.

aspirin 100 mg capsule: enteric, 84

<table>
<thead>
<tr>
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<th>No. of Rpts</th>
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<td>1</td>
<td>..</td>
<td>14.96</td>
<td>6.10</td>
<td>Astrix [YN]</td>
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aspirin 100 mg tablet: enteric, 84

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<td>1</td>
<td>1</td>
<td>..</td>
<td>14.05</td>
<td>6.10</td>
<td>* Cartia [AS]</td>
<td>* Pharmacy Action Low Dose Aspirin [GQ]</td>
</tr>
</tbody>
</table>

**CLOPIDOGREL**

*Authority required*

For use in patients pre- and post-angioplasty

*Note*

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

clopidogrel 75 mg tablet, 28

<table>
<thead>
<tr>
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<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
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<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>3</td>
<td>..</td>
<td>15.70</td>
<td>6.10</td>
<td>* Clopidogrel GH [GQ]</td>
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clopidogrel 75 mg tablet, 28

<table>
<thead>
<tr>
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<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>1</td>
<td>3</td>
<td>..</td>
<td>15.70</td>
<td>6.10</td>
<td>* APO-Clopidogrel [TX]</td>
<td>* Iscover [AV]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Plavix [SW]</td>
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<td></td>
<td></td>
<td></td>
<td>* Chem mart Clopidogrel [CH]</td>
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<td></td>
<td></td>
<td></td>
<td>* Piax [AF]</td>
</tr>
<tr>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Terry White Chemists</td>
</tr>
<tr>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td>Clopidogrel [TW]</td>
</tr>
</tbody>
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**BLOOD SUBSTITUTE AND PERFUSION SOLUTIONS**

**IRRIGATING SOLUTIONS**

*Salt solutions*

**SODIUM CHLORIDE**

sodium chloride 0.9% (4.5 g/500 mL) solution, 1 x 500 mL bottle

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
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<th>DPMQ $</th>
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<td>10.67</td>
<td>6.10 Baxter Healthcare Pty Ltd [BX]</td>
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</table>

sodium chloride 0.9% (9 g/1000 mL) solution, 1 x 1000 mL bottle

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
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**CARDIOVASCULAR SYSTEM**

**VASOPROTECTIVES**

**AGENTS FOR TREATMENT OF HEMORRHOIDS AND ANAL FISSURES FOR TOPICAL USE**

*Other agents for treatment of hemorrhoids and anal fissures for topical use*

**ZINC OXIDE + PERU BALSAM + BENZYL BENZOATE**

zinc oxide 10.75% (107.5 mg/g) + peru balsam 1.88% (18.8 mg/g) + benzyl benzoate 1.25% (12.5 mg/g) ointment, 50 g

<table>
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<tbody>
<tr>
<td>4039N</td>
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<td>14.78</td>
<td>6.10 Anusol [JT]</td>
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</table>

zinc oxide 300 mg + peru balsam 50 mg + benzyl benzoate 33 mg suppository, 12

<table>
<thead>
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<td>6.10 Anusol [JT]</td>
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**DERMATOLOGICALS**

**ANTIFUNGALS FOR DERMATOLOGICAL USE**

**ANTIFUNGALS FOR TOPICAL USE**

**Antibiotics**

**NYSTATIN**

nystatin 100 000 international units/g cream, 15 g

<table>
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<tr>
<td>4001N</td>
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<td>12.83</td>
<td>6.10 Mycostatin [FM]</td>
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### Imidazole and triazole derivatives

#### CLOTRIMAZOLE

<table>
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<tr>
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<th>clotrimazole 1% (10 mg/g) cream, 20 g</th>
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<td>9.18</td>
<td>6.10</td>
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#### KETOCONAZOLE

*Restricted benefit*

Severe seborrhoeic dermatitis

ketoconazole 2% (20 mg/g) shampoo, 100 mL

<table>
<thead>
<tr>
<th></th>
<th>ketoconazole 2% (20 mg/g) shampoo, 100 mL</th>
<th>4007X</th>
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ketoconazole 2% (20 mg/g) shampoo, 60 mL

<table>
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<td>Nizoral 2% [JT]</td>
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#### MICONAZOLE

miconazole 2% solution, 30 mL

<table>
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<tr>
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<td>Daktarin Tincture [JT]</td>
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miconazole nitrate 2% (20 mg/g) cream, 30 g

<table>
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<tr>
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<td>Daktarin [JT]</td>
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miconazole nitrate 2% (20 mg/g) cream, 40 g

<table>
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<td>Resolve Thrush [EO]</td>
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#### Other antifungals for topical use

#### AMOROLFINE

*Restricted benefit*

Onychomycosis

amorolfin 5% application, 5 mL

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<thead>
<tr>
<th></th>
<th>amorolfin 5% application, 5 mL</th>
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#### CICLOPIROX

*Restricted benefit*

Severe seborrhoeic dermatitis

ciclopirox olamine 1.5% (15 mg/g) shampoo, 60 mL

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<tr>
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<th>ciclopirox olamine 1.5% (15 mg/g) shampoo, 60 mL</th>
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<th>No of Rpts</th>
<th>Premium $</th>
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<td>Stieprox Liquid [GK]</td>
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</table>

#### TERBINAFINE

*Restricted benefit*

Tinea pedis

terbinafine 1% gel, 15 g

<table>
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<th></th>
<th>terbinafine 1% gel, 15 g</th>
<th>4463X</th>
<th>Max Qty</th>
<th>No of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
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<td>Lamisil DermGel [NC]</td>
</tr>
</tbody>
</table>

terbinafine hydrochloride 1% cream, 15 g

<table>
<thead>
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<th>4473K</th>
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<td></td>
<td>Lamisil [NC]</td>
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</tbody>
</table>
### TOLNAFTATE

tolnaftate 0.07% (700 microgram/g) spray, 100 g

<table>
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<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
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<tr>
<td>‡1</td>
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<td>Tinaderm [BN]</td>
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### ANTIFUNGALS FOR SYSTEMIC USE

#### TERBINAFINE

Authority required

Onychomycosis due to dermatophyte infection proven by microscopy or culture and confirmed by an approved pathology provider

terbinafine 250 mg tablet, 42

<table>
<thead>
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<td>* Lamisil (Novartis</td>
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<td></td>
<td>* Tamsil [QA]</td>
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<td>* Terbinafine GH [GQ]</td>
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<td></td>
<td></td>
<td>* Tinasil [AF]</td>
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### EMOLLIENTS AND PROTECTIVES

#### EMOLLIENTS AND PROTECTIVES

Silicone products

#### DIMETHICONE-350 + GLYCEROL

Restricted benefit

For colostomy and ileostomy use

Restricted benefit

For use by paraplegic and quadriplegic patients

Restricted benefit

For use with surgical appliances

dimethicone-350 15% (150 mg/g) + glycerol 2% (20 mg/g) cream, 500 g

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
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<td>26.75</td>
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<td>Silic 15 [EO]</td>
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</tbody>
</table>

dimethicone-350 15% (150 mg/g) + glycerol 2% (20 mg/g) cream, 75 g

<table>
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Soft paraffin and fat products

#### WOOL ALCOHOLS

wool alcohols 6% (60 mg/g) ointment, 100 g

<table>
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Carbamide products

#### UREA

urea 10% (100 mg/g) cream, 100 g

<table>
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<td>13.11</td>
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<td>Calmurid [OL]</td>
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</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>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
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<tbody>
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### SKIN EMOLLIENT

**SKIN EMOLLIENT Bath oil 500 mL, 1**

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<th>Premium</th>
<th>DPMQ</th>
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<td>2</td>
<td>..</td>
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Alpha Keri Bath Oil [MT]

<table>
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<th>Max Qty</th>
<th>Pack</th>
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<th>Premium</th>
<th>DPMQ</th>
<th>MRVSN</th>
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<td>2</td>
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OV Bath Oil [EO]

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<td>20.19</td>
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Hamilton Skin Therapy Oil [KY]

**SKIN EMOLLIENT Lotion 500 mL, 1**

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Alpha Keri Lotion [MT]

### PROTECTIVES AGAINST UV-RADIATION

**Protectives against UV-radiation for topical use**

### SUNSCREENS

**SUNSCREENS Cream 75 g, 1**

<table>
<thead>
<tr>
<th>Max Qty</th>
<th>Pack</th>
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<td>18.39</td>
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Sunsense Sensitive SPF 50+ [EO]

**SUNSCREENS Lotion (non-alcoholic) 125 mL, 1**

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Aquasun Lotion SPF 18 [PF]

<table>
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<th>Premium</th>
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<td>..</td>
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<td>18.39</td>
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</table>

Sunsense Ultra SPF 50+ [EO]

### ANTIPRURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC.

**Antiperspirants, Incl. Antihistamines, Anesthetics, Etc.**

**Anesthetics for topical use**

**LIGNOCAINE**

Lignocaine hydrochloride anhydrous 2% (20 mg/mL) oral liquid, 200 mL

<table>
<thead>
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<tbody>
<tr>
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<td>99.72</td>
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<td></td>
</tr>
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Xylocaine Viscous [AP]

**Other antipruritics**

**PINE TAR WITH TRIETHANOLAMINE LAURYL SULFATE**

*Note*
For patients who have failed to respond to simple moisturising agents.

**PINE TAR with TRIETHANOLAMINE LAURYL SULFATE Solution 23 mg-60 mg per mL (2.3%-6%), 500 mL, 1**

<table>
<thead>
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<th>Premium</th>
<th>DPMQ</th>
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<tbody>
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<td>23.26</td>
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Pinetarsol [EO]

### ANTIPSORIATICS

**Antipsoriatics for topical use**

**Tars**

**COAL TAR SOLUTION + PHENOL + SULFUR-PRECIPITATED**

coal tar solution 5% + phenol 0.5% + sulfur-precipitated 0.5% gel, 30 g

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Egopsoryl-TA [EO]

### ANTIBIOTICS AND CHEMOTHERAPEUTICS FOR DERMATOLOGICAL USE

**Antibiotics for topical use**

**Other antibiotics for topical use**

**MUPIROCIN**

*Restricted benefit*
For the topical treatment of secondarily infected traumatic skin lesions
mupirocin 2% (20 mg/g) cream, 15 g
4348W

<table>
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<tbody>
<tr>
<td>‡1</td>
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<td>17.59</td>
<td>6.10</td>
<td>...</td>
<td>Bactroban [GK]</td>
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</tbody>
</table>

mupirocin 2% (20 mg/g) ointment, 15 g
4350Y

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
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<th>DPMQ $</th>
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<td>Bactroban [GK]</td>
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</tbody>
</table>

CHEMOTHERAPEUTICS FOR TOPICAL USE

Antivirals

▪ PODOPHYLLOTOXIN

Authority required
For the treatment of ano-genital warts

podophyllotoxin 0.15% (1.5 mg/g) cream, 5 g
4390C

<table>
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podophyllotoxin 0.5% solution, 3.5 mL
4566H

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</table>

Other chemotherapeutics

▪ INGENOL MEBUTATE

Authority required
Solar keratosis
Clinical criteria:
Patient must require topical drug therapy on the face and scalp as field treatment for clinically visible and subclinical lesions where other standard treatments are inappropriate.

ingenol mebutate 0.015% gel, 3 x 470 mg tubes
2464Q

<table>
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<td>139.60</td>
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<td>Picato [LO]</td>
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ingenol mebutate 0.05% gel, 2 x 470 mg tubes
2468X

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CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS

CORTICOSTEROIDS, PLAIN

▪ BETAMETHASONE VALERATE

Corticosteroids, potent (group III)

betamethasone (as valerate) 0.1% (1 mg/g) cream, 30 g
4131K

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<tr>
<th>Max Qty Packs</th>
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<td>Betnovate [QA]</td>
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betamethasone (as valerate) 0.1% (1 mg/g) ointment, 30 g
4132L

<table>
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<td>22.77</td>
<td>6.10</td>
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<td>Betnovate [QA]</td>
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</table>

▪ MOMETASONE

Note
Application to large areas of skin for longer than four weeks is not recommended.
mometasone furoate 0.1% (1 mg/g) cream, 50 g

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<tr>
<th>Max Qty Packs</th>
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<td>33.82</td>
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<td>Elocon [MK]</td>
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</tbody>
</table>

mometasone furoate 0.1% (1 mg/g) ointment, 50 g

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<th>DPMQ $</th>
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### ANTISEPTICS AND DISINFECTANTS

#### Iodine products

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<td>Betadine Antiseptic Liquid [SW]</td>
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### OTHER DERMATOLOGICAL PREPARATIONS

#### Medicated shampoos

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<th>DPMQ $</th>
<th>MRVSN $</th>
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<tbody>
<tr>
<td>1</td>
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<td>19.18</td>
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<td>Sebitar [EO]</td>
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### OTHER DERMATOLOGICAL PREPARATIONS

#### Medicated shampoos

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### SELENIUM SULFIDE

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<tbody>
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### Wart and anti-corn preparations

#### LACTIC ACID + SALICYLIC ACID

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<thead>
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<td>24.48</td>
<td>6.10</td>
<td></td>
<td>Polytar [GK]</td>
</tr>
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</table>

### Other dermatologicals

#### DICLOFENAC

**Authority required**

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.

**Note**

Maximum quantity of four tubes (original + 3 repeats) in 12 months.
| Product Description                                                                 | Brand Name and Manufacturer | DPMQ $ | MRVSN $ | Premium $ | Max Qty Packs | No. of Rpts | |---------------------------------|-----------------------------|--------|---------|------------|--------------|-------------|--------||
| diclofenac sodium 3% gel, 25 g                                                   | Solaraze 3% Gel [CS]         | 58.53  | 6.10    | 1          | 3            |             |        | |
| ichthammol Cream 5 mg-10 mg-10 mg per g (0.5%-1%-1%), 50 g, 1                    | Egoderm Cream [EO]           | 18.44  | 6.10    | 1          | 2            |             |        | |
| ichthammol 1% (10 mg/g) + zinc oxide 15% (150 mg/g) ointment, 50 g               | Egoderm Ointment [EO]        | 18.44  | 6.10    | 1          | 2            |             |        | |
| imiquimod 5% cream, 12 x 250 mg sachets                                          | Aldara | 135.72 | 6.10    | 1          | 1            |             |        | |
| imiquimod 5% cream, 2 x 2 g pump packs                                           | Aldara Pump | 135.72 | 6.10    | 1          | 1            |             |        | |
| panthenol conditioner, 200 g                                                    | SebiRinse [EO]               | 14.59  | 6.10    | 1          | 2            |             |        | |
| paraffin light liquid 3.5% (35 mg/mL) + cocoamphodiacetate disodium 3% (30 mg/mL) lotion, 500 mL | Hamilton Skin Therapy Wash [KY] | 21.08  | 6.10    | 1          | 2            |             |        | |

**ICHTHHAMMOL**

Note: For patients who have failed to respond to simple moisturising agents.

**ICHTHHAMMOL + ZINC OXIDE**

Note: For patients who have failed to respond to simple moisturising agents.

**IMIQUIMOD**

Authority required

Primary treatment of histopathologically confirmed superficial basal cell carcinoma where other standard treatments are inappropriate and topical drug therapy is required

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.
- ZINC OXIDE + MAIZE STARCH + CHLORPHENESIN + TALC-PURIFIED
  zinc oxide 25% (250 mg/g) + maize starch 55.85% (558.5 mg/g) + chlorphenesin 1% (10 mg/g) + talc-purified 18.07% (180.7 mg/g) powder: dusting, 100 g

4497Q

<table>
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<tr>
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<th>Packs</th>
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<td>Z.S.C. [QA]</td>
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</table>

- GENITO URINARY SYSTEM AND SEX HORMONES

- GYNECOLOGICAL ANTIINFECTIVES AND ANTISEPTICS

  - Antiinfectives and Antiseptics, Excl. Combinations with Corticosteroids
    - Antibiotics
      - NYSTATIN
        nystatin 20,000 international units/g vaginal cream, 75 g

4013F

<table>
<thead>
<tr>
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<tr>
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<td>Nilstat [QA]</td>
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</table>

  - Imidazole derivatives
    - CLOTRIMAZOLE
      clotrimazole 1% (10 mg/g) cream, 35 g

4016J

<table>
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<td>* Pharmacy Action FemCream [GQ]</td>
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<tr>
<td></td>
<td></td>
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<td>..</td>
<td>15.42</td>
<td>* APO-Clotrimazole 6 Day Cream [TX]</td>
<td></td>
</tr>
</tbody>
</table>

      clotrimazole 2% (20 mg/g) cream, 20 g

4017K

<table>
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<th>No. of Rpts</th>
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- OTHER GYNECOLOGICALS

- ACETIC ACID + HYDROXYQUINOLINE + RICINOLEIC ACID
  acetic acid 0.94% + hydroxyquinoline sulfate 0.025% + ricinoleic acid 0.75% vaginal gel, 100 g

4434J

<table>
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- UROLOGICALS

- Drugs used in erectile dysfunction

- ALPROSTADIL
  Authority required
  Males with vasculogenic, psychogenic or neurogenic erectile dysfunction
  Clinical criteria:
  Patient must have a specific accepted war-caused or service-related disability.
  Authorisation will not be given for any additional prescriptions within 6 months or for any increased quantities or repeats.

alprostadil 10 microgram injection [1 x 10 microgram vial] (&) inert substance diluent [1 syringe], 1 pack

10031Y

<table>
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<tr>
<th>Max Qty</th>
<th>Packs</th>
<th>No. of Rpts</th>
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<td>*105.82</td>
<td>6.10</td>
<td>Caverject [PF]</td>
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</table>

alprostadil 20 microgram injection [1 x 20 microgram vial] (&) inert substance diluent [1 syringe], 1 pack

10030X

<table>
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<th>Max Qty</th>
<th>Packs</th>
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<td>*133.18</td>
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<td>Caverject [PF]</td>
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</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.
## GENITO URINARY SYSTEM AND SEX HORMONES

### Schedule of Pharmaceutical Benefits

**sildenafil 100 mg tablet, 4**

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**sildenafil 25 mg tablet, 4**

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<td></td>
<td>Sildenafil Actavis [UA]</td>
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<td>APO-Sildenafil [TX]</td>
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<tr>
<td></td>
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<td>Viagra [PF]</td>
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**sildenafil 50 mg tablet, 4**

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<td>Sildenafil Actavis [UA]</td>
<td></td>
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<td>Vasafl 50 [QA]</td>
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<td>Viagra [PF]</td>
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## TADALAFIL

**Authority required**

Specific accepted war-caused or service-related disabilities for males with vasculogenic, psychogenic or neurogenic erectile dysfunction.

Authorisation will not be given for any additional prescriptions within 6 months or for any increased quantities or repeats.

**tadalafil 10 mg tablet, 4**

<table>
<thead>
<tr>
<th>Max Qty</th>
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<tbody>
<tr>
<td>1</td>
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<td>98.96</td>
<td>6.10</td>
<td>Cialis [LY]</td>
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**tadalafil 20 mg tablet, 4**

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<th>Premium</th>
<th>DPMQ</th>
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<tbody>
<tr>
<td>1</td>
<td>5</td>
<td>..</td>
<td>98.96</td>
<td>6.10</td>
<td>Cialis [LY]</td>
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</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.

**vardenafil 10 mg tablet, 4**

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<td>73.13</td>
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**vardenafil 20 mg tablet, 4**

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<th>Premium</th>
<th>DPMQ</th>
<th>MRVSN</th>
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<td>83.86</td>
<td>6.10</td>
<td>Levitra [BN]</td>
<td></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.

**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**

<table>
<thead>
<tr>
<th>Max Qty</th>
<th>Packs</th>
<th>No. of Rpts</th>
<th>Premium</th>
<th>DPMQ</th>
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<td>13.89</td>
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<td>Uracol [GN]</td>
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</tr>
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</table>

## DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY

### Alpha-adrenoreceptor antagonists

## ALFUZOSIN

**Authority required**

Treatment of benign prostatic hyperplasia where surgery is inappropriate, or where other drug treatment has failed or is contraindicated.
### Alfuzosin Hydrochloride 10 mg Tablet: Modified Release, 30 Tablets

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium</th>
<th>DPMQ</th>
<th>MRVSN</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>5</td>
<td>..</td>
<td>63.70</td>
<td>6.10</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.

**Dutasteride 500 Microgram + Tamsulosin Hydrochloride 400 Microgram Capsule: Modified Release, 30 Tablets**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium</th>
<th>DPMQ</th>
<th>MRVSN</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>1</td>
<td>5</td>
<td>..</td>
<td>35.63</td>
<td>6.10</td>
<td>Duodart 500ug/400ug [GK]</td>
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</tbody>
</table>

### Tamsulosin

**Authority required**

Treatment of benign prostatic hyperplasia where surgery is inappropriate, or where other drug treatment has failed or is contraindicated.

**Tamsulosin Hydrochloride 400 Microgram Tablet: Modified Release, 30 Tablets**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium</th>
<th>DPMQ</th>
<th>MRVSN</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>5</td>
<td>..</td>
<td>63.70</td>
<td>6.10</td>
<td>Flomaxtra [LS]</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.

**Terazosin 1 mg Tablet [7 Tablets] (&) Terazosin 2 mg Tablet [7 Tablets], 14 Tablets**

<table>
<thead>
<tr>
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<th>MRVSN</th>
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</thead>
<tbody>
<tr>
<td>‡1</td>
<td>..</td>
<td>..</td>
<td>20.39</td>
<td>6.10</td>
<td>Hytrin [GO]</td>
</tr>
</tbody>
</table>

**Terazosin 10 mg Tablet, 28 Tablets**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium</th>
<th>DPMQ</th>
<th>MRVSN</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>5</td>
<td>..</td>
<td>86.40</td>
<td>6.10</td>
<td>Hytrin [GO]</td>
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</table>

**Terazosin 2 mg Tablet, 28 Tablets**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium</th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>5</td>
<td>..</td>
<td>42.03</td>
<td>6.10</td>
<td>Hytrin [GO]</td>
</tr>
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</table>

**Terazosin 5 mg Tablet, 28 Tablets**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium</th>
<th>DPMQ</th>
<th>MRVSN</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
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<td>5</td>
<td>..</td>
<td>58.53</td>
<td>6.10</td>
<td>Hytrin [GO]</td>
</tr>
</tbody>
</table>

### Testosterone-5-alpha Reductase Inhibitors

** Dutasteride **

**Authority required**

Benign prostatic hyperplasia

**Clinical criteria:**

Patient must be one in whom surgery is inappropriate; OR
Patient must have failed to respond to other drug treatment or other drug treatment must be contraindicated.

**Dutasteride 500 Microgram Capsule, 30 Tablets**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
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<th>DPMQ</th>
<th>MRVSN</th>
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<td>30.77</td>
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<td>Avodart [GK]</td>
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</table>

** Finasteride **

**Authority required**

Treatment of benign prostatic hyperplasia where surgery is inappropriate, or where other drug treatment has failed or is contraindicated.

**Finasteride 5 mg Tablet, 28 Tablets**

<table>
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<tr>
<th>Max Qty Packs</th>
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<td>91.60</td>
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<td>* Finpro [RZ]</td>
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<table>
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<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>1</td>
<td>5</td>
<td>..</td>
<td>91.60</td>
<td>6.10</td>
<td>* Pharmacy Choice Finasteride [RI]</td>
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FINASTERIDE FOR SYSTEMIC USE

ANTIINFECTIONS FOR SYSTEMIC USE

ANTIBACTERIALS FOR SYSTEMIC USE

MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS

Macrolides

AZITHROMYCIN

Restrict benefit
Upper and lower respiratory tract infections

AZITHROMYCIN 500 mg tablet, 3

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

ANTINEOPLASTIC AGENTS

ANTIMETABOLITES

Pyrimidine analogues

FLUOROURACIL

fluorouracil 5% (50 mg/g) cream, 20 g

IMMUNOSUPPRESSANTS

Tumor necrosis factor alpha (TNF-) inhibitors

IMMUNOSUPPRESSANTS

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
(1) (b) Proven erosive rheumatoid arthritis without end-stage disease;
(2) 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;
(3) No history of active tuberculosis requiring treatment in the last 3 years;
(4) No history of opportunistic infection in the last 2 months;
(5) 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
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;
- (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

**infliximab 100 mg injection, 1 x 100 mg vial**

<table>
<thead>
<tr>
<th>Max Qty</th>
<th>No. of Rpts</th>
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<td>847.32</td>
<td>6.10</td>
<td>Remicade [JC]</td>
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**MUSCULO-SKELETAL SYSTEM**

**ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS**

Acetic acid derivatives and related substances

**DICLOFENAC + MISOPROSTOL**

*Authority required*

Patients requiring an NSAID in whom a risk of upper gastrointestinal complications is high or with a history of peptic ulcer disease

**diclofenac sodium 50 mg + misoprostol 200 microgram tablet, 60**

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<tr>
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<td>38.12</td>
<td>6.10</td>
<td>Arthrotec 50 [PF]</td>
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</table>

**TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN**

**TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN**

Preparations with salicylic acid derivatives

**METHYL SALICYLATE**

methyl salicylate 25% (0.25 mL/mL) liniment, 100 mL

<table>
<thead>
<tr>
<th>Max Qty</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
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<tbody>
<tr>
<td>‡1</td>
<td>1</td>
<td>..</td>
<td>10.28</td>
<td>6.10</td>
<td>Gold Cross [BI]</td>
</tr>
</tbody>
</table>

methyl salicylate 50% (500 mg/g) ointment, 100 g

<table>
<thead>
<tr>
<th>Max Qty</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
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</thead>
<tbody>
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<td>1</td>
<td>..</td>
<td>12.51</td>
<td>6.10</td>
<td>Gold Cross [BI]</td>
</tr>
</tbody>
</table>

**METHYL SALICYLATE + MENTHOL + EUCALYPTUS OIL**

methyl salicylate 25% (250 mg/g) + menthol 4% (40 mg/g) + eucalyptus oil 10% (100 mg/g) cream, 100 g

<table>
<thead>
<tr>
<th>Max Qty</th>
<th>No. of Rpts</th>
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<th>DPMQ $</th>
<th>MRVSN $</th>
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<tr>
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<td>14.36</td>
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**DRUGS FOR TREATMENT OF BONE DISEASES**

**DRUGS AFFECTING BONE STRUCTURE AND MINERALIZATION**

Bisphosphonates

**RISEDRONATE**

*Authority required*

For preservation of bone mineral density in patients on long-term glucocorticoid therapy where patients are undergoing continuous treatment with a dose equal to or greater than 7.5 mg of prednisone or equivalent per day. Prescribers need to demonstrate that the patient has been on continuous therapy for 3 months or more and demonstrate that the patient is osteopenic (bone mineral density t-score of less than -1.0)
Schedule of Pharmaceutical Benefits

MUSCULO-SKELETAL SYSTEM

### RIZEDRONATE SODIUM Tablet 35 mg (enteric coated), 4

<table>
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<th>Max Qty</th>
<th>Packs</th>
<th>No. of Rpts</th>
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<tbody>
<tr>
<td>1</td>
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<td>..</td>
<td>42.11</td>
<td>6.10</td>
<td></td>
<td>Actonel EC [UA]</td>
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### risedronate sodium 35 mg tablet, 4

<table>
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<th>Packs</th>
<th>No. of Rpts</th>
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<th>DPMQ</th>
<th>MRVSN</th>
<th>Brand Name and Manufacturer</th>
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<td>1</td>
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<td>..</td>
<td>42.11</td>
<td>6.10</td>
<td></td>
<td>Acris Once-a-Week [AF]</td>
</tr>
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<td></td>
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<td></td>
<td>APO-Risedronate [TX]</td>
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<td>Risedronate-GA [GN]</td>
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<td>Risedronate Sandoz [SZ]</td>
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### risedronate sodium 5 mg tablet, 28

<table>
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<th>No. of Rpts</th>
<th>Premium</th>
<th>DPMQ</th>
<th>MRVSN</th>
<th>Brand Name and Manufacturer</th>
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<td>1</td>
<td>5</td>
<td>..</td>
<td>42.11</td>
<td>6.10</td>
<td></td>
<td>Actonel [UA]</td>
</tr>
</tbody>
</table>

---

### Bisphosphonates, combinations

- **ALENDRONATE + COLECALCIFEROL**
  
  **Authority required**
  
  For preservation of bone mineral density in patients on long-term glucocorticoid therapy where patients are undergoing continuous treatment with a dose equal to or greater than 7.5 mg of prednisone or equivalent per day. Prescribers need to demonstrate that the patient has been on continuous therapy for 3 months or more and demonstrate that the patient is osteopenic (bone mineral density t-score of less than -1.0)

- **alendronate 70 mg + colecalciferol 140 microgram tablet, 4**
  
<table>
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<th>Packs</th>
<th>No. of Rpts</th>
<th>Premium</th>
<th>DPMQ</th>
<th>MRVSN</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
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<td>1</td>
<td>5</td>
<td>..</td>
<td>45.51</td>
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<td>Alendronate plus D3-DRLA [RZ]</td>
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<tr>
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<td></td>
<td>FonatPLUS [AF]</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Fosamax Plus 70 mg/140 mcg [MK]</td>
</tr>
</tbody>
</table>

- **alendronate 70 mg + colecalciferol 70 microgram tablet, 4**
  
<table>
<thead>
<tr>
<th>Max Qty</th>
<th>Packs</th>
<th>No. of Rpts</th>
<th>Premium</th>
<th>DPMQ</th>
<th>MRVSN</th>
<th>Brand Name and Manufacturer</th>
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<td></td>
<td>Alendronate plus D3-DRLA [RZ]</td>
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<td></td>
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<td></td>
<td></td>
<td>FonatPLUS [AF]</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Fosamax Plus [MK]</td>
</tr>
</tbody>
</table>

- **ALENDRONATE + COLECALCIFEROL (&) 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)

- **alendronate 70 mg + colecalciferol 140 microgram tablet [4] (&) calcium (as carbonate) 500 mg tablet [48], 1 pack**
  
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<th>Packs</th>
<th>No. of Rpts</th>
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<th>DPMQ</th>
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<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>†1</td>
<td>5</td>
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<td>45.51</td>
<td>6.10</td>
<td></td>
<td>Fosamax Plus D-Cal [MK]</td>
</tr>
</tbody>
</table>

- **RIZEDRONATE (&) 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)

- **RIZEDRONATE 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**
  
<table>
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<th>Packs</th>
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<th>DPMQ</th>
<th>MRVSN</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>†1</td>
<td>5</td>
<td>..</td>
<td>45.73</td>
<td>6.10</td>
<td></td>
<td>Actonel EC Combi [UA]</td>
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</tbody>
</table>

- **RIZEDRONATE (&) CALCIUM CARBONATE + COLECALCIFEROL**
  
  **Authority required**
  
  For preservation of bone mineral density in patients on long-term glucocorticoid therapy where patients are undergoing continuous treatment with a dose equal to or greater than 7.5 mg of prednisone or equivalent per day. Prescribers need to
demonstrate that the patient has been on continuous therapy for 3 months or more and demonstrate that the patient is osteopenic (bone mineral density t-score of less than -1.0).

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

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
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<th>DPMQ $</th>
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<td>6.10</td>
<td>Actonel EC Combi D [UA]</td>
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### NERVOUS SYSTEM

### ANALGESICS

#### OPIOIDS

*Natural opium alkaloids*

#### MORPHINE

**Caution**
The risk of drug dependence is high.

**Restricted benefit**
Chronic severe disabling pain not responding to non-narcotic analgesics

**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.

**morphine sulfate 200 mg tablet: modified release, 28 tablets**

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<tr>
<td>4349X</td>
<td>28</td>
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<td>122.20</td>
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<td>MS Cont [MF]</td>
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### OTHER ANALGESICS AND ANTIPYRETICS

#### Salicylic acid and derivatives

#### ASPIRIN + CODEINE

*aspirin 300 mg + codeine phosphate 8 mg tablet: dispersible, 40*

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#### Anilides

#### PARACETAMOL + CODEINE

*paracetamol 500 mg + codeine phosphate 15 mg tablet, 20*

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<tr>
<td>4170L</td>
<td>20</td>
<td>...</td>
<td>10.07</td>
<td>6.10</td>
<td>Prodeine 15 [SW]</td>
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</table>

*paracetamol 500 mg + codeine phosphate 8 mg tablet, 40*

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<td>11.03</td>
<td>6.10</td>
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*paracetamol 500 mg + codeine phosphate 8 mg tablet, 50*

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<td>4171M</td>
<td>50</td>
<td>...</td>
<td>13.20</td>
<td>6.10</td>
<td>Codalgin [FM]</td>
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</table>

*paracetamol 500 mg + codeine phosphate hemihydrate 15 mg tablet, 20*

<table>
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<th>Brand Name and Manufacturer</th>
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<td>10186D</td>
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<td>10.07</td>
<td>6.10</td>
<td>Pharmacy Action Paracetamol Plus Codeine [GQ]</td>
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Other analgesics and antipyretics

#### GABAPENTIN

**Authority required**
To be approved for the treatment of refractory neuropathic pain not controlled by other drugs
<table>
<thead>
<tr>
<th><strong>NERVOUS SYSTEM</strong></th>
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### Gabapentin 100 mg capsule, 100

<table>
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<tr>
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<td>12.95</td>
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<td>* APO-Gabapentin [TX]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Gabapentin Aspen 100 [FM]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Neurontin [PF]</td>
</tr>
<tr>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>* Nupentin 100 [AF]</td>
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</table>

### Gabapentin 300 mg capsule, 100

<table>
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<td>* Gabapentin [HH]</td>
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<td></td>
<td>* Gabapentin Aspen 300 [FM]</td>
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<td></td>
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<td></td>
<td>* GenRx Gabapentin [GX]</td>
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<td>* Nupentin 300 [AF]</td>
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### Gabapentin 400 mg capsule, 100

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<td>34.94</td>
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<td></td>
<td></td>
<td></td>
<td>* Gabapentin Aspen 400 [FM]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* GenRx Gabapentin [GX]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Nupentin 400 [AF]</td>
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### Gabapentin 600 mg tablet, 100

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<td>* Gabapentin Aspen 600 [FM]</td>
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<td></td>
<td></td>
<td></td>
<td>* Neurontin [PF]</td>
</tr>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* GenRx Gabapentin [GX]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Nupentin Tabs [AF]</td>
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### Gabapentin 800 mg tablet, 100

<table>
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<td></td>
<td></td>
<td></td>
<td>* GenRx Gabapentin [GX]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Neurontin [PF]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Nupentin Tabs [AF]</td>
</tr>
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</table>

### PSYCHOLEPTICS

#### ANXIOLYTICS

**Benzodiazepine derivatives**

### Bromazepam

**Authority required**

Patients with terminal disease

**Authority required**

Patients with refractory phobic or anxiety states

**Note**

For short-term use and palliative care. This drug should not be used as the first line of treatment. Other PBS-listed benzodiazepines should have been adequately tried and found to be ineffective or inappropriate. Authorities for increased quantities and/or repeats may be granted to patients with terminal disease, and other patients who have been shown to be dependent on this item by an unsuccessful attempt at gradual withdrawal.

### Bromazepam 3 mg tablet, 30

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<td>4150K</td>
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<td>..</td>
<td>*29.82</td>
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<td>Lexotan [RO]</td>
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### Bromazepam 6 mg tablet, 30

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<tr>
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<td>..</td>
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<td>Lexotan [RO]</td>
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</table>

**Azaspirodecanedione derivatives**

### Buspirone

**Authority required**

For the short-term treatment of anxiety

### Buspirone Hydrochloride 10 mg tablet, 50

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
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<td>..</td>
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<td>Buspar [QA]</td>
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### Buspirone Hydrochloride 5 mg tablet, 50

<table>
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<tbody>
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<td>..</td>
<td>38.33</td>
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<td>Buspar [QA]</td>
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</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.

flunitrazepam 1 mg tablet, 30
4216X

<table>
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<tr>
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<td>Hypnodorm [AF]</td>
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Benzodiazepine related drugs

- ZOPICLONE
  Restricted benefit
  For the short-term treatment of insomnia

zopiclone 7.5 mg tablet, 30
4522B

<table>
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<th>Brand Name and Manufacturer</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>1</td>
<td>..</td>
<td>22.10</td>
<td>6.10</td>
<td></td>
<td>* APO-Zopiclone [TX]</td>
<td>* Chemmart Zopiclone [CH]</td>
</tr>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>* Imrest [AF]</td>
<td>* Terry White Chemists</td>
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<td></td>
<td></td>
<td>Zopiclone [TW]</td>
</tr>
</tbody>
</table>

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.

nicotine 10 mg/16 hours patch, 7
4577X

<table>
<thead>
<tr>
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<tr>
<td>2</td>
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<td>*55.12</td>
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<td>Nicorette Patch [JT]</td>
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nicotine 14 mg/24 hours patch, 7
4572P

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<tr>
<td>2</td>
<td>..</td>
<td>*54.90</td>
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<td>QuitX [AF]</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>*69.08</td>
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nicotine 15 mg/16 hours patch, 7
4578Y

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<tr>
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<td>*60.30</td>
<td>6.10</td>
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<td>Nicorette Patch [JT]</td>
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nicotine 21 mg/24 hours patch, 7
4573Q

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<td>QuitX [AF]</td>
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<td>*69.08</td>
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nicotine 5 mg/16 hours patch, 7
4576W

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<th>DPMQ $</th>
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<td>6.10</td>
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## ANTIPARASITIC PRODUCTS, INSECTICIDES AND REPELLENTS

### ANTIPARASITIC PRODUCTS, INSECTICIDES AND REPELLENTS

#### ANTHELMINTICS

**ANTINEMATODAL AGENTS**  
*Benzimidazole derivatives*

### MEBENDAZOLE

mebendazole 100 mg tablet, 6

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
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<td>Vermox [IA]</td>
</tr>
</tbody>
</table>

### RESPIRATORY SYSTEM

#### NASAL PREPARATIONS

**DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE**  
*Sympathomimetics, plain*

### OXYMETAZOLINE

oxymetazoline hydrochloride 0.05% (500 microgram/mL) nasal spray, 15 mL

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>‡1</td>
<td></td>
<td>17.49</td>
<td>6.10</td>
<td></td>
<td>Drixine [BN]</td>
</tr>
</tbody>
</table>

oxymetazoline hydrochloride 0.05% (500 microgram/mL) nasal spray, 18 mL

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>‡1</td>
<td></td>
<td>17.10</td>
<td>6.10</td>
<td></td>
<td>Logicin Rapid Relief [OA]</td>
</tr>
</tbody>
</table>

**Antiallergic agents, excl. corticosteroids**

### CROMOGLYCATIE

cromoglycate sodium 2% (20 mg/mL) nasal spray, 26 mL

<table>
<thead>
<tr>
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<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>‡1</td>
<td>5</td>
<td>23.25</td>
<td>6.10</td>
<td></td>
<td>Rynacrom [SW]</td>
</tr>
</tbody>
</table>

### LEVOCABASTINE

levocabastine 0.05% (500 microgram/mL) nasal spray, 100 actuations

<table>
<thead>
<tr>
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<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>‡1</td>
<td>2</td>
<td>18.58</td>
<td>6.10</td>
<td></td>
<td>Livostin [JT]</td>
</tr>
</tbody>
</table>

**Corticosteroids**

### BUDESONIDE

*Restricted benefit*

Severe intractable rhinitis

budesonide 64 microgram/actuation nasal spray, 120 actuations

<table>
<thead>
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<th>No. of Rpts</th>
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<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>‡1</td>
<td></td>
<td>39.03</td>
<td>6.10</td>
<td></td>
<td>Budamax Aqueous [PM]</td>
</tr>
</tbody>
</table>

**Other nasal preparations**

### IPRATROPIUM

*Restricted benefit*

Severe intractable rhinorrhoea, associated with perennial rhinitis, unresponsive to insufflated nasal steroids

ipratropium bromide anhydrous 21 microgram/actuation nasal spray, 180 actuations

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>‡1</td>
<td>5</td>
<td>23.93</td>
<td>6.10</td>
<td></td>
<td>Atrouvent Nasal Aqueous [BY]</td>
</tr>
</tbody>
</table>
RESPIRATORY SYSTEM

ipratropium bromide anhydrous 42 microgram/actuation nasal spray, 180 actuations

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No of Rpts</th>
<th>Premium</th>
<th>DPMQ</th>
<th>MRVSN</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>4090G</td>
<td></td>
<td>5</td>
<td>30.81</td>
<td>6.10</td>
<td>Atrvent Nasal Forte [BY]</td>
</tr>
</tbody>
</table>

NASAL DECONGESTANTS FOR SYSTEMIC USE

Sympathomimetics

PSEUDOEPHEDRINE

 pseudoephedrine hydrochloride 60 mg tablet, 12

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No of Rpts</th>
<th>Premium</th>
<th>DPMQ</th>
<th>MRVSN</th>
</tr>
</thead>
<tbody>
<tr>
<td>4029C</td>
<td>1, 4</td>
<td>10.61</td>
<td>6.10</td>
<td></td>
</tr>
</tbody>
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COUGH AND COLD PREPARATIONS

EXPECTORANTS, EXCL. COMBINATIONS WITH COUGH SUPPRESSANTS

Expectorants

AMMONIUM + SENEGA ROOT

 ammonium bicarbonate 25 mg/mL + senega root 25 mg/mL oral liquid, 200 mL

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No of Rpts</th>
<th>Premium</th>
<th>DPMQ</th>
<th>MRVSN</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>4074K</td>
<td>†1</td>
<td>4</td>
<td>9.52</td>
<td>6.10</td>
<td>Gold Cross [BI]</td>
</tr>
</tbody>
</table>

COUGH SUPPRESSANTS, EXCL. COMBINATIONS WITH EXPECTORANTS

Opium alkaloids and derivatives

PHOLCODINE

 pholcodine 1 mg/mL oral liquid, 100 mL

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No of Rpts</th>
<th>Premium</th>
<th>DPMQ</th>
<th>MRVSN</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>4071G</td>
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<td>2</td>
<td>9.36</td>
<td>6.10</td>
<td>Gold Cross [BI]</td>
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</tbody>
</table>

ANTIHISTAMINES FOR SYSTEMIC USE

ANTIHISTAMINES FOR SYSTEMIC USE

Piperazine derivatives

CETIRIZINE

cetirizine hydrochloride 10 mg tablet, 30

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No of Rpts</th>
<th>Premium</th>
<th>DPMQ</th>
<th>MRVSN</th>
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<tbody>
<tr>
<td>4175R</td>
<td>†1</td>
<td></td>
<td>26.28</td>
<td>6.10</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>29.99</td>
<td>6.10</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>33.21</td>
<td>6.10</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>39.79</td>
<td>6.10</td>
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</table>

Other antihistamines for systemic use

FEXOFENADINE

 fexofenadine hydrochloride 120 mg tablet, 30

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No of Rpts</th>
<th>Premium</th>
<th>DPMQ</th>
<th>MRVSN</th>
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</thead>
<tbody>
<tr>
<td>4238C</td>
<td>1</td>
<td></td>
<td>29.76</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>35.05</td>
<td>6.10</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>47.47</td>
<td>6.10</td>
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</table>

 fexofenadine hydrochloride 60 mg tablet, 20

<table>
<thead>
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<th>No of Rpts</th>
<th>Premium</th>
<th>DPMQ</th>
<th>MRVSN</th>
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<tbody>
<tr>
<td>4237B</td>
<td>3</td>
<td></td>
<td>55.33</td>
<td>6.10</td>
</tr>
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</table>
### SENSORY ORGANS

#### OPTHALMOLOGICALS

**DECONGESTANTS AND ANTIALLERGICS**  
*Sympathomimetics used as decongestants*

#### NAPHAZOLINE

**naphazoline hydrochloride 0.1% eye drops, 15 mL**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>..</td>
<td>15.43</td>
<td>6.10</td>
<td></td>
<td>Albalon Liquifilm [AG]</td>
</tr>
</tbody>
</table>

#### NAPHAZOLINE + ANTAZOLINE

**naphazoline hydrochloride 0.05% + antazoline phosphate 0.5% eye drops, 15 mL**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>‡1</td>
<td>1</td>
<td>15.14</td>
<td>6.10</td>
<td></td>
<td>Albalon-A [AG]</td>
</tr>
</tbody>
</table>

**Other antiallergics**

#### LEVOCABASTINE

**levocabastine 0.05% eye drops, 4 mL**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>‡1</td>
<td>1</td>
<td>18.58</td>
<td>6.10</td>
<td></td>
<td>Livostin [JT]</td>
</tr>
</tbody>
</table>

### OTOLOGICALS

#### OTHER OTOLOGICALS

**Indifferent preparations**

#### CARBAMIDE PEROXIDE

**carbamide peroxide 6.5% ear drops, 12 mL**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>‡1</td>
<td>..</td>
<td>17.66</td>
<td>6.10</td>
<td></td>
<td>Ear Clear for Ear Wax Removal [KY]</td>
</tr>
</tbody>
</table>

#### DICHLOREDBENZENE WITH CHLORBUTOL AND ARACHIS OIL

**DICHLOREDBENZENE with CHLORBUTOL and ARACHIS OIL Ear drops, ortho-dichlorobenzene 140 mg per mL, para-dichlorobenzene 20 mg per mL, chlorbutol 50 mg per mL, arachis oil 573 mg per mL, 10 mL, 1**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>‡1</td>
<td>..</td>
<td>14.42</td>
<td>6.10</td>
<td></td>
<td>Cerumol [UN]</td>
</tr>
</tbody>
</table>

#### DOCUSATE

**docusate sodium 0.5% (5 mg/mL) ear drops, 10 mL**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
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<tbody>
<tr>
<td>‡1</td>
<td>..</td>
<td>14.81</td>
<td>6.10</td>
<td></td>
<td>Waxsol [HM]</td>
</tr>
</tbody>
</table>

### VARIOUS

#### ALL OTHER THERAPEUTIC PRODUCTS

**ALL OTHER THERAPEUTIC PRODUCTS**

*Drugs for treatment of hyperkalemia and hyperphosphatemia*
POLYSTYRENE SULFONATE SODIUM

polystyrene sulfonate sodium 999.3 mg/g powder, 454 g

<table>
<thead>
<tr>
<th>Max Qty</th>
<th>Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>‡1</td>
<td>2</td>
<td>..</td>
<td>71.46</td>
<td>6.10</td>
<td>..</td>
<td>Resonium-A [SW]</td>
</tr>
</tbody>
</table>

ALL OTHER NON-THERAPEUTIC PRODUCTS

LUBRICATING AGENT

lubricating agent jelly, 100 g

<table>
<thead>
<tr>
<th>Max Qty</th>
<th>Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>..</td>
<td>..</td>
<td>10.47</td>
<td>6.10</td>
<td>..</td>
<td>Lubri-Gel [PP]</td>
</tr>
</tbody>
</table>

Other non-therapeutic auxiliary products

BANDAGE ABSORBENT WOOL

bandage absorbent wool 10 cm x 3 m bandage, 1

<table>
<thead>
<tr>
<th>Max Qty</th>
<th>Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>..</td>
<td>..</td>
<td>20.66</td>
<td>6.10</td>
<td>..</td>
<td>Surepress 650948 [CC]</td>
</tr>
</tbody>
</table>

BANDAGE CALICO

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.

bandage calico large bandage: triangular, 1 bandage

<table>
<thead>
<tr>
<th>Max Qty</th>
<th>Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>‡1</td>
<td>2</td>
<td>..</td>
<td>13.38</td>
<td>6.10</td>
<td>..</td>
<td>Handy 36361414 [BV]</td>
</tr>
</tbody>
</table>

BANDAGE COMPRESSION

Note
Treatment of varices and oedema associated with venous disease and lymphoedema; contraindicated in arterial disease. 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.

bandage compression bandage: four layer, 1 bandage

<table>
<thead>
<tr>
<th>Max Qty</th>
<th>Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>5</td>
<td>..</td>
<td>..</td>
<td>*160.01</td>
<td>6.10</td>
<td>..</td>
<td>Profore Lite 66050415 [SN]</td>
</tr>
</tbody>
</table>

bandage compression bandage: four layer, 1 bandage

<table>
<thead>
<tr>
<th>Max Qty</th>
<th>Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>5</td>
<td>..</td>
<td>..</td>
<td>*234.36</td>
<td>6.10</td>
<td>..</td>
<td>Profore 66050016 [SN]</td>
</tr>
</tbody>
</table>

BANDAGE COMPRESSION

Note
Treatment of varices and oedema associated with venous disease and lymphoedema; contraindicated in arterial disease. 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.

BANDAGE-COMPRESSION Bandage, short stretch, 8 cm x 2.6 m, 1

<table>
<thead>
<tr>
<th>Max Qty</th>
<th>Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>5</td>
<td>..</td>
<td>..</td>
<td>*76.11</td>
<td>6.10</td>
<td>..</td>
<td>Comprilan 01027-00 [BV]</td>
</tr>
</tbody>
</table>

bandage compression 10 cm x 3 m bandage: high stretch, 1 bandage

<table>
<thead>
<tr>
<th>Max Qty</th>
<th>Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>5</td>
<td>..</td>
<td>..</td>
<td>*73.26</td>
<td>6.10</td>
<td>..</td>
<td>Surepress 650947 [CC]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>*152.96</td>
<td>6.10</td>
<td>..</td>
<td>Tensopress 71723-00 [BV]</td>
</tr>
</tbody>
</table>
### BANDAGE COMPRESSION

**Note**

Treatment of varices and oedema associated with venous disease and lymphoedema; contraindicated in arterial disease.

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.

<table>
<thead>
<tr>
<th>Bandage Compression</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bandage Compression 10 cm x 3.5 m bandage: high stretch, 1 bandage</td>
<td>4657D</td>
<td>5</td>
<td>..</td>
<td>..</td>
<td>78.91</td>
<td>Setopress 3505 [MH]</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.

Bandage can be left in situ for up to 7 days as per manufacturer’s instructions.

<table>
<thead>
<tr>
<th>Bandage Compression</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bandage compression bandage: two layer, 1 bandage</td>
<td>4050E</td>
<td>1</td>
<td>..</td>
<td>..</td>
<td>43.02</td>
<td>Coban 2 [MM]</td>
</tr>
</tbody>
</table>

### BANDAGE RETENTION COHESIVE HEAVY

**bandage retention cohesive heavy 10 cm x 1.3 m bandage, 1**

<table>
<thead>
<tr>
<th>Bandage Retention Cohesive Heavy</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bandage retention cohesive heavy 10 cm x 1.3 m bandage, 1</td>
<td>4813H</td>
<td>2</td>
<td>..</td>
<td>..</td>
<td>21.42</td>
<td>Peg 7423 [MM]</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Bandage Retention Cohesive Heavy</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bandage retention cohesive heavy 10 cm x 2 m bandage, 1</td>
<td>4660G</td>
<td>2</td>
<td>..</td>
<td>..</td>
<td>19.70</td>
<td>Coban 1584 [MM]</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Bandage Retention Cohesive Heavy</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bandage retention cohesive heavy 15 cm x 1.3 m bandage, 1</td>
<td>4814J</td>
<td>2</td>
<td>..</td>
<td>..</td>
<td>28.52</td>
<td>Peg 7425 [MM]</td>
</tr>
</tbody>
</table>

<table>
<thead>
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<th>Bandage Retention Cohesive Heavy</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bandage retention cohesive heavy 5 cm x 1.3 m bandage, 1</td>
<td>4811F</td>
<td>2</td>
<td>..</td>
<td>..</td>
<td>14.36</td>
<td>Peg 7420 [MM]</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Bandage Retention Cohesive Heavy</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bandage retention cohesive heavy 7.5 cm x 1.3 m bandage, 1</td>
<td>4812G</td>
<td>2</td>
<td>..</td>
<td>..</td>
<td>17.64</td>
<td>Peg 7422 [MM]</td>
</tr>
</tbody>
</table>

### BANDAGE RETENTION COHESIVE LIGHT

**Note**

Smith & Nephew products are distributed via the three major wholesalers, API, Sigma and Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS agreed pricing from distributors other than those aforementioned.

<table>
<thead>
<tr>
<th>Bandage Retention Cohesive Light</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bandage retention cohesive light 10 cm x 2 m bandage, 1</td>
<td>4662J</td>
<td>2</td>
<td>..</td>
<td>..</td>
<td>31.42</td>
<td>Handygauze Cohesive 8635 [BV]</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Bandage Retention Cohesive Light</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bandage retention cohesive light 2.5 cm x 2 m bandage, 2</td>
<td>4718H</td>
<td>1</td>
<td>..</td>
<td>..</td>
<td>13.52</td>
<td>Handygauze Cohesive 8631 [BV]</td>
</tr>
</tbody>
</table>
**BANDAGE RETENTION COTTON CREPE**

Note

Smith & Nephew products are distributed via the three major wholesalers, API, Sigma and Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS agreed pricing from distributors other than those aforementioned.

**BANDAGE TUBULAR**

Note

Molnlycke Health Care products are distributed through leading pharmacy distributors. To best ensure product availability at the RPBS agreed prices, special arrangements have been made with API and Independence Australia Health Solutions (IAHS). IAHS orders can be placed on: Tel: 1300 788 855; or Email: customerservice@independenceaustralia.com. Molnlycke Health Care is not able to ensure product availability or pricing on listed products beyond these two suppliers.
### Bandage Tubular

#### Bandage Tubular (Finger) Complete pack including applicator, 1

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>†1</td>
<td></td>
<td></td>
<td>15.32</td>
<td>6.10</td>
<td>Tubigrip E 1547 [MH]</td>
</tr>
</tbody>
</table>

#### 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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<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>†1</td>
<td></td>
<td></td>
<td>18.11</td>
<td>6.10</td>
<td>Tubegauz 0501633 [SS]</td>
</tr>
</tbody>
</table>

#### Bandage Tubular Long Stocking

**Note**
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<th>DPMQ $</th>
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<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>†1</td>
<td></td>
<td></td>
<td>28.47</td>
<td>6.10</td>
<td>Tubifast 2438 [MH]</td>
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<table>
<thead>
<tr>
<th>Max Qty Packs</th>
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<th>DPMQ $</th>
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</thead>
<tbody>
<tr>
<td>†1</td>
<td></td>
<td></td>
<td>27.06</td>
<td>6.10</td>
<td>Tubifast 2436 [MH]</td>
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<table>
<thead>
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<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>†1</td>
<td></td>
<td></td>
<td>23.10</td>
<td>6.10</td>
<td>Tubifast 2434 [MH]</td>
</tr>
</tbody>
</table>

#### Bandage Tubular Short Stocking

**Note**
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<thead>
<tr>
<th>Max Qty Packs</th>
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<th>DPMQ $</th>
<th>MRVSN $</th>
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</thead>
<tbody>
<tr>
<td>†1</td>
<td></td>
<td></td>
<td>25.72</td>
<td>6.10</td>
<td>Tubigrip 1481 [MH]</td>
</tr>
</tbody>
</table>
**VARIOUS**

**BANDAGE ZINC PASTE**

**Note**
Used as an adjunct in the management of leg ulceration and associated eczema and skin conditions.

**bandage zinc paste 10 cm x 9.1 m bandage, 1**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>4670T</td>
<td>2</td>
<td>..</td>
<td>*29.12</td>
<td>6.10</td>
<td>Flexidress 650941 [CC]</td>
</tr>
</tbody>
</table>

**BANDAGE ZINC PASTE**

**Note**
Used as an adjunct in the management of leg ulceration and associated eczema and skin conditions.

**bandage zinc paste 7.5 cm x 6 m bandage, 1**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>4669R</td>
<td>2</td>
<td>3</td>
<td>*30.00</td>
<td>6.10</td>
<td>Steripaste 3610 [MH]</td>
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</tbody>
</table>

**BANDAGE ZINC PASTE**

**Note**
Used as an adjunct in the management of leg ulceration and associated eczema and skin conditions.

**bandage zinc paste 7.5 cm x 6 m bandage, 1**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
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<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>4760M</td>
<td>2</td>
<td></td>
<td>82.66</td>
<td>6.10</td>
<td>Viscopaste 4948 [SN]</td>
</tr>
</tbody>
</table>

**BANDAGE ZINC PASTE**

**Note**
Used as an adjunct in the management of leg ulceration and associated eczema and skin conditions.

**bandage zinc paste 80 cm (stockings) bandage, 4**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>4937W</td>
<td>‡1</td>
<td>3</td>
<td>95.42</td>
<td>6.10</td>
<td>Iodosorb 66000747 [SN]</td>
</tr>
</tbody>
</table>

**BETAINE + POLYAMINOPROPYL BIGUANIDE**

**Note**
Used as an adjunct in the management of leg ulceration and associated eczema and skin conditions.

**bandage zinc paste 80 cm (stockings) bandage, 4**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>2525X</td>
<td>1</td>
<td>..</td>
<td>27.01</td>
<td>6.10</td>
<td>Prontosan Wound Irrigation Solution [BR]</td>
</tr>
</tbody>
</table>

**CADEXOMER-IODINE**

**Note**
Suitable for yellow sloughy infected and malodorous wounds.

**DRESSING with CADEXOMER IODINE Sheets 17 g (10 cm x 8 cm), 2, 1**

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>4937W</td>
<td>‡1</td>
<td>..</td>
<td>163.92</td>
<td>6.10</td>
<td>Iodosorb 66051360 [SN]</td>
</tr>
</tbody>
</table>
## DRESSING with CADEXOMER IODINE Sheets 5 g (6 cm x 4 cm), 5, 1

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>†1</td>
<td>2</td>
<td>..</td>
<td>107.59</td>
<td>6.10</td>
<td>Iodosorb 66051330 [SN]</td>
</tr>
</tbody>
</table>

### cadexomer-iodine 3 g powder: dusting sterile, 7 x 3 g sachets

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>†1</td>
<td>2</td>
<td>..</td>
<td>70.65</td>
<td>6.10</td>
<td>Iodosorb Powder 66051070</td>
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</table>

### cadexomer-iodine 50% (500 mg/g) ointment, 2 x 20 g tubes

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>†1</td>
<td>2</td>
<td>..</td>
<td>112.77</td>
<td>6.10</td>
<td>Iodosorb Ointment 66051230</td>
</tr>
</tbody>
</table>

### cadexomer-iodine 50% (500 mg/g) ointment, 4 x 10 g tubes

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>†1</td>
<td>2</td>
<td>..</td>
<td>113.83</td>
<td>6.10</td>
<td>Iodosorb Ointment 66051240</td>
</tr>
</tbody>
</table>

### cadexomer-iodine 8 cm x 6 cm dressing, 3 x 10 g sheets

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>†1</td>
<td>2</td>
<td>..</td>
<td>155.54</td>
<td>6.10</td>
<td>Iodosorb 66051340 [SN]</td>
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</tbody>
</table>

### DRESSING ACTIVATED CHARCOAL MALODOROUS WOUND

#### dressing activated charcoal malodorous wound 10 cm x 10 cm dressing, 10

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>†1</td>
<td>..</td>
<td>..</td>
<td>79.32</td>
<td>6.10</td>
<td>CarboFLEX 403202 [CC]</td>
</tr>
</tbody>
</table>

#### dressing activated charcoal malodorous wound 10.5 cm x 10.5 cm dressing, 1

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>10</td>
<td>..</td>
<td>..</td>
<td>*101.26</td>
<td>6.10</td>
<td>Actisorb Plus MAP105 [KI]</td>
</tr>
</tbody>
</table>

#### dressing activated charcoal malodorous wound 15 cm x 20 cm dressing, 5

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>†1</td>
<td>..</td>
<td>..</td>
<td>90.21</td>
<td>6.10</td>
<td>CarboFLEX 403204 [CC]</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.

#### DRESSING-ALGINATE (CAVITY WOUND) Rope 2 g, 1

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>10</td>
<td>..</td>
<td>..</td>
<td>*109.46</td>
<td>6.10</td>
<td>Sorbsan 1411 [UM]</td>
</tr>
</tbody>
</table>

#### DRESSING-ALGINATE (CAVITY WOUND) Rope 2 g, 5

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
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<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>..</td>
<td>..</td>
<td>*115.60</td>
<td>6.10</td>
<td>Kaltostat 168117 [CC]</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.

Coloplast dressings are available via a range of distributors. However, Coloplast's principal agreement to ensure correct RPBS Price to Pharmacy and ready supply has been secured with Independence Australia on 1300 788 855 and BrightSky on 1300 290 400. Please note that Coloplast is unable to guarantee ready supply or rebate for price differences on purchases outside these distributors.

#### dressing alginate cavity wound 2 g (40 cm) rope, 6 x 2 g

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>..</td>
<td>..</td>
<td>*138.06</td>
<td>6.10</td>
<td>Comfeel SeaSorb Filler 3740</td>
</tr>
</tbody>
</table>

### DRESSING ALGINATE SUPERFICIAL WOUND

**Note**

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#### dressing alginate cavity wound 2 g (40 cm) rope, 6 x 2 g

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<tr>
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<tbody>
<tr>
<td>2</td>
<td>..</td>
<td>..</td>
<td>*138.06</td>
<td>6.10</td>
<td>Comfeel SeaSorb Filler 3740</td>
</tr>
</tbody>
</table>

**DRESSING**
This dressing should be used only on moderately to heavily exuding wounds and should remain in place until saturated or for a maximum of 3 days.

**DRESSING ALGINATE SUPERFICIAL WOUND**

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<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>4683L</td>
<td>1</td>
<td>..</td>
<td>91.42</td>
<td>6.10</td>
<td>Kaltostat 168212 [CC]</td>
</tr>
</tbody>
</table>

**DRESSING ALGINATE SUPERFICIAL WOUND**

Note

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</tr>
</thead>
<tbody>
<tr>
<td>4700J</td>
<td>1</td>
<td>..</td>
<td>110.35</td>
<td>6.10</td>
<td>Algisite M 66000520 [SN]</td>
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</tbody>
</table>

<table>
<thead>
<tr>
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<th>No. of Rpts</th>
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<th>DPMQ $</th>
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<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>4691X</td>
<td>1</td>
<td>..</td>
<td>263.04</td>
<td>6.10</td>
<td>Algisite M 66000521 [SN]</td>
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</tbody>
</table>

**DRESSING ALGINATE SUPERFICIAL WOUND**

Note

Coloplast dressings are available via a range of distributors. However, Coloplast’s principal agreement to ensure correct RPBS Price to Pharmacy and ready supply has been secured with Independence Australia on 1300 788 855 and BrightSky on 1300 290 400. Please note that Coloplast is unable to guarantee ready supply or rebate for price differences on purchases outside these distributors.

<table>
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<tr>
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<td>6.10</td>
<td>Sorbsan 1410 [UM]</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>*90.46</td>
<td></td>
<td>Comfeel SeaSorb Dressing 3710 [CT]</td>
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**DRESSING FILM**

**dressing film 10 cm x 12 cm dressing, 4**

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**dressing film 15 cm x 20 cm dressing, 1**

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<tr>
<td>4688R</td>
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<td>*31.00</td>
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**dressing film 6 cm x 7 cm dressing, 8**

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**DRESSING FILM**

Note
### DRESSING FILM ISLAND

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<tr>
<td>Op-Site Flexigrid 4629 [SN]</td>
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<tr>
<td>Tegaderm Transparent Island 3582 [MM]</td>
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### DRESSING FOAM HEAVY EXUDATE

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<td>Allevyn 66007637 [SN]</td>
<td>132.80</td>
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### DRESSING FOAM MODERATE EXUDATE

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<tr>
<td>Cavicare 4563 [SN]</td>
<td>99.44</td>
<td>6.10</td>
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### DRESSING FOAM MODERATE EXUDATE

<table>
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<th>MRVSN $</th>
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<tr>
<td>Cavicare 4563 [SN]</td>
<td>99.44</td>
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</table>

### 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.
VARIOUS

VARIOUS

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 foam moderate exudate 12.5 cm x 12.5 cm dressing, 10

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<td>138.27</td>
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<td>Allevyn Adhesive 66000044 [SN]</td>
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**DRESSING FOAM WITH SILICONE**

**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 agreed pricing from distributors other than those aforementioned.

**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 agreed pricing from distributors other than those aforementioned.

dressing foam with silicone 10.3 cm x 10.3 cm dressing, 10

<table>
<thead>
<tr>
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dressing foam with silicone 12.9 cm x 12.9 cm dressing, 10

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dressing foam with silicone 15.4 cm x 15.4 cm dressing, 10

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dressing foam with silicone 21 cm x 21 cm dressing, 10

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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.

dressing foam with silicone and silver 10 cm x 10 cm dressing, 5

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<td>Mepilex Ag [MH]</td>
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dressing foam with silicone and silver 10 cm x 10 cm dressing, 5

<table>
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**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.

dressing foam with silicone heavy exudate 10 cm x 10 cm dressing, 10

<table>
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dressing foam with silicone heavy exudate 10 cm x 10 cm dressing, 10

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</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.

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
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<td>Allevyn Gentle Border 66800269 [SN]</td>
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### DRESSING FOAM WITH SILICONE LIGHT EXUDATE

**Note**

Molnlycke Healthcare products are distributed through leading pharmacy distributors. To best ensure product availability at RPBS agreed prices, special arrangements have been made with API and Independence Australia Health Solutions (IAHS). IAHS orders can be placed on: Tel: 1300 788 855; or Email customerservice@independenceaustralia.com. Molnlycke Healthcare are not able to ensure product availability or pricing on listed products beyond these two suppliers.

<table>
<thead>
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### DRESSING FOAM WITH SILICONE MODERATE EXUDATE

**Note**

Molnlycke Healthcare products are distributed through leading pharmacy distributors. To best ensure product availability at RPBS agreed prices, special arrangements have been made with API and Independence Australia Health Solutions (IAHS). IAHS orders can be placed on: Tel: 1300 788 855; or Email customerservice@independenceaustralia.com. Molnlycke Healthcare are not able to ensure product availability or pricing on listed products beyond these two suppliers.

<table>
<thead>
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### DRESSING FOAM WITH SILVER

**Authority required**

For wounds where there is evidence of critical colonisation and for well-assessed chronic wounds that have not responded to conventional dressings

**Note**

Smith & Nephew products are distributed via the three major wholesalers, API, Sigma & Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS pricing from distributors other than those aforementioned.

<table>
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<td>Allevyn Ag Non-Adhesive 66800086 [SN]</td>
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</table>
## DRESSING GAUZE ABSORBENT

**Note**

Smith & Nephew products are distributed via the three major wholesalers, API, Sigma, and Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS agreed pricing from distributors other than those aforementioned.

### dressing gauze absorbent 10 cm x 10 cm pad, 100

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### dressing gauze absorbent 5 cm x 5 cm pad, 100

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## DRESSING GAUZE EYE

### dressing gauze eye pad, 12

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<td>Curity 4112 [KE]</td>
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</table>

## DRESSING GAUZE PARAFFIN

**Note**

Smith & Nephew products are distributed via the three major wholesalers, API, Sigma, 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.

### dressing gauze paraffin 10 cm x 10 cm dressing, 10

<table>
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<tr>
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<td>21.96</td>
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<td>Jelonet 7404 [SN]</td>
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## DRESSING GAUZE PARAFFIN WITH CHLORHEXIDINE ACETATE

**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.

### dressing gauze paraffin with chlorhexidine acetate 10 cm x 10 cm dressing, 10

<table>
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<td>Bactigras 7457 [SN]</td>
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</table>
- **DRESSING HYDROACTIVE CAVITY WOUND**
  
  Note
  Smith & Nephew products are distributed via the three major wholesalers, API, Sigma & Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS pricing from distributors other than those aforementioned.

<table>
<thead>
<tr>
<th>dressing hydroactive cavity wound 10 cm x 10 cm dressing, 5</th>
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<tbody>
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<table>
<thead>
<tr>
<th>dressing hydroactive cavity wound 5 cm x 6 cm dressing, 10</th>
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- **DRESSING HYDROACTIVE DEBRIDEMENT**

  Note
  Hartmann wound dressings are available through HARTMANN and Independence Australia only. If you would like to order Hartmann Wound Care products, please call HARTMANN customer service on 1800 805 839 or Independence Australia on 1300 788 855.

<table>
<thead>
<tr>
<th>DRESSING-HYDROACTIVE (DEBRIDEMENT) Dressings 4 cm, 10, 1</th>
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<th>DRESSING-HYDROACTIVE (DEBRIDEMENT) Dressings 5.5 cm, 10, 1</th>
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<th>DRESSING-HYDROACTIVE (DEBRIDEMENT) Dressings 7.5 cm x 7.5 cm, 10, 1</th>
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- **DRESSING HYDROACTIVE SUPERFICIAL WOUND HIGH EXUDATE SEMI-PERMEABLE ABSORBENT FOAM**

  dressing hydroactive superficial wound high exudate semi-permeable absorbent foam 10 cm x 10 cm (foam alternative) dressing, 10

<table>
<thead>
<tr>
<th>dressing hydroactive superficial wound high exudate semi-permeable absorbent foam 10 cm x 10 cm (foam alternative) dressing, 10</th>
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</thead>
<tbody>
<tr>
<td>Max.Qty Packs</td>
<td>No. of Rpts</td>
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</table>

  dressing hydroactive superficial wound high exudate semi-permeable absorbent foam 11 cm x 11 cm dressing: island, 10 dressings

<table>
<thead>
<tr>
<th>dressing hydroactive superficial wound high exudate semi-permeable absorbent foam 11 cm x 11 cm dressing: island, 10 dressings</th>
<th>4695D</th>
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<tbody>
<tr>
<td>Max.Qty Packs</td>
<td>No. of Rpts</td>
</tr>
<tr>
<td>‡1</td>
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</tr>
</tbody>
</table>

  dressing hydroactive superficial wound high exudate semi-permeable absorbent foam 15 cm x 18 cm (foam alternative) dressing, 5

<table>
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<tr>
<th>dressing hydroactive superficial wound high exudate semi-permeable absorbent foam 15 cm x 18 cm (foam alternative) dressing, 5</th>
<th>4693B</th>
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<td>‡1</td>
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  dressing hydroactive superficial wound high exudate semi-permeable absorbent foam 18 cm x 18 cm dressing: island, 5 dressings

<table>
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<td>No. of Rpts</td>
</tr>
<tr>
<td>‡1</td>
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</tr>
</tbody>
</table>

- **DRESSING HYDROACTIVE SUPERFICIAL WOUND HIGH EXUDATE SEMI-PERMEABLE ABSORBENT FOAM**

  Note
  Coloplast dressings are available via a range of distributors. However, Coloplast’s principal agreement to ensure correct RPBS Price to Pharmacy and ready supply has been secured with Independence Australia on 1300 788 855 and BrightSky.
VARIOUS

on 1300 290 400. Please note that Coloplast is unable to guarantee ready supply or rebate for price differences on purchases outside these distributors.

dressing hydroactive superficial wound high exudate semi-permeable absorbent foam 10 cm x 10 cm pad: waterproof, 10 pads

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>‡1</td>
<td>1</td>
<td>..</td>
<td>88.27</td>
<td>6.10</td>
<td>Biatain Non-adhesive 3410</td>
</tr>
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[CT]

dressing hydroactive superficial wound high exudate semi-permeable absorbent foam 12 cm x 12 cm pad: waterproof, 10 pads

<table>
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<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>‡1</td>
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<td>..</td>
<td>97.29</td>
<td>6.10</td>
<td>Biatain Adhesive 3420</td>
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[CT]

dressing hydroactive superficial wound high exudate semi-permeable absorbent foam 15 cm x 15 cm pad: waterproof, 5 pads

<table>
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<tr>
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<td>86.79</td>
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[CT]

dressing hydroactive superficial wound high exudate semi-permeable absorbent foam 18 cm x 18 cm pad: waterproof, 5 pads

<table>
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<td>94.16</td>
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<td>Biatain Adhesive 3423</td>
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[CT]

### 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 light exudate 10 cm x 10 cm dressing, 5

<table>
<thead>
<tr>
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<tbody>
<tr>
<td>2</td>
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<td>*113.60</td>
<td>6.10</td>
<td>Allevyn Thin 66047578</td>
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[SN]

dressing hydroactive superficial wound light exudate 5 cm x 6 cm dressing, 10

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<th>Brand Name and Manufacturer</th>
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<tr>
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</table>

[SN]

### DRESSING HYDROACTIVE SUPERFICIAL WOUND MODERATE EXUDATE

**Note**

Smith & Nephew products are distributed via the three major wholesalers, API, Sigma & Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS pricing from distributors other than those aforementioned.

dressing hydroactive superficial wound moderate exudate 10 cm x 10 cm dressing, 5

<table>
<thead>
<tr>
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<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>2</td>
<td>1</td>
<td>..</td>
<td>*88.96</td>
<td>6.10</td>
<td>Cutinova Hydro 66047443</td>
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[SN]

dressing hydroactive superficial wound moderate exudate 5 cm x 6 cm dressing, 10

<table>
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<td>52.88</td>
<td>6.10</td>
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[SN]

### DRESSING HYDROCOLLOID CAVITY WOUND

**Note**

This dressing should remain in place until saturated or strike through occurs for a maximum of 7 days.

dressing hydrocolloid cavity wound paste, 30 g

<table>
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<tr>
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<tbody>
<tr>
<td>10</td>
<td>..</td>
<td>..</td>
<td>*145.46</td>
<td>6.10</td>
<td>DuoDERM Paste H7930</td>
</tr>
</tbody>
</table>

[CC]
This dressing should remain in place until saturated or strike through occurs for a maximum of 7 days. Coloplast dressings are available via a range of distributors. However, Coloplast’s principal agreement to ensure correct RPBS Price to Pharmacy and ready supply has been secured with Independence Australia on 1300 788 855 and BrightSky on 1300 290 400. Please note that Coloplast is unable to guarantee ready supply or rebate for price differences on purchases outside these distributors.

### Dressing Hydrocolloid Cavity Wound Paste, 50 g

<table>
<thead>
<tr>
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<tbody>
<tr>
<td></td>
<td>2</td>
<td>3</td>
<td>..</td>
<td>43.56</td>
<td>6.10</td>
<td>Comfeel Paste 4701 [CT]</td>
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</table>

### Dressing Hydrocolloid Superficial Wound Light Exudate

**Note**

This dressing should be applied to a thickness of 3 mm to 5 mm. It should be covered with a hydrocolloid dressing and may be left in place for up to 7 days.

<table>
<thead>
<tr>
<th>4907G</th>
<th>Max Qty Packs</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>‡1</td>
<td>1</td>
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<td>72.06</td>
<td>6.10</td>
<td>DuoDERM Extra Thin H7955 [CC]</td>
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</tbody>
</table>

### Dressing Hydrocolloid Superficial Wound Light Exudate

**Note**

This dressing should be applied to a thickness of 3 mm to 5 mm. It should be covered with a hydrocolloid dressing and may be left in place for up to 7 days.

<table>
<thead>
<tr>
<th>4924E</th>
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<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td></td>
<td>‡1</td>
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<td>..</td>
<td>70.12</td>
<td>6.10</td>
<td>Comfeel Plus Transparent 3533 [CT]</td>
</tr>
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</table>

### Dressing Hydrocolloid Superficial Wound Light Exudate

<table>
<thead>
<tr>
<th>4888G</th>
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<th>DPMO $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>‡1</td>
<td>1</td>
<td>..</td>
<td>42.06</td>
<td>6.10</td>
<td>Comfeel Plus Transparent 3530 [CT]</td>
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### Dressing Hydrocolloid Superficial Wound Light Exudate

<table>
<thead>
<tr>
<th>4889H</th>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
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<th>DPMO $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>‡1</td>
<td>1</td>
<td>..</td>
<td>84.86</td>
<td>6.10</td>
<td>Comfeel Plus Transparent 3536 [CT]</td>
</tr>
</tbody>
</table>

### Dressing Hydrocolloid Superficial Wound Light Exudate

**Note**

This dressing should be applied to a thickness of 3 mm to 5 mm. It should be covered with a hydrocolloid dressing and may be left in place for up to 7 days.

<table>
<thead>
<tr>
<th>4947J</th>
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<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td></td>
<td>‡1</td>
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<td>..</td>
<td>48.49</td>
<td>6.10</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.

<table>
<thead>
<tr>
<th>4897R</th>
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<th>DPMO $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>2</td>
<td>1</td>
<td>..</td>
<td>81.74</td>
<td>6.10</td>
<td>DuoDERM CGF H7660 [CC]</td>
</tr>
</tbody>
</table>
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.

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 HYDROFIBRE ALTERNATE TO ALGINATES

dressing hydrofibre alternate to alginates 10 cm x 10 cm dressing, 10

**2797F**
Max Qty Packs  | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer
--- | --- | --- | --- | --- | ---
1 | 1 | .. | 101.32 | 6.10 | Aquacel Extra 420672 [CC]

Dressing hydrofibre alternate to alginates 15 cm x 15 cm dressing, 5

**2803M**
Max Qty Packs  | No. of Rpts | Premium $ | DPMQ $ | MRVSN $ | Brand Name and Manufacturer
--- | --- | --- | --- | --- | ---
2 | 1 | .. | *209.04 | 6.10 | Aquacel Extra 420673 [CC]
### Dressing Hydrofibre Alternate to Alginites

**4698G**

<table>
<thead>
<tr>
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<th>Brand Name and Manufacturer</th>
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<tr>
<td>‡1</td>
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<td>..</td>
<td>84.05</td>
<td>6.10</td>
<td>Aquacel 403770 [CC]</td>
</tr>
</tbody>
</table>

### Dressing Hydrofibre Gelling Fibre

**Note**

Smith & Nephew products are distributed via the three major wholesalers, API, Sigma and Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS agreed pricing from distributors other than those aforementioned.

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>‡1</td>
<td>1</td>
<td>..</td>
<td>100.19</td>
<td>6.10</td>
<td>Durafiber 66800560 [SN]</td>
</tr>
</tbody>
</table>

### Dressing Hydrofibre Gelling Fibre

**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.

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>‡1</td>
<td>1</td>
<td>..</td>
<td>83.65</td>
<td>6.10</td>
<td>Durafiber 66800563 [SN]</td>
</tr>
</tbody>
</table>

### Dressing Hydrofibre with Silver

**Authority required**

Wound critical colonisation or chronic wounds that have not responded to conventional dressings

**Clinical criteria:**

- Patient must have a wound where there is evidence of critical colonisation; OR
- Patient must have a well-assessed chronic wound that has not responded to conventional dressings.

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>‡1</td>
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<td>..</td>
<td>262.40</td>
<td>6.10</td>
<td>Aquacel Ag 403708 [CC]</td>
</tr>
</tbody>
</table>

### Dressing Hydrogel

**Dressing Hydrogel 10 cm x 10 cm dressing, 20**

<table>
<thead>
<tr>
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<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tbody>
<tr>
<td>1</td>
<td>..</td>
<td>114.38</td>
<td>6.10</td>
<td></td>
<td>Sorbact Absorption Dressing S98222 [QL]</td>
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</table>

### Dressing Hydrogel Amorphous

**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.

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
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<tbody>
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<td>97.45</td>
<td>6.10</td>
<td>DuoDERM Gel H7987 [CC]</td>
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### Dressing Hydrogel Amorphous

**Note**

<table>
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<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>3</td>
<td>3</td>
<td>..</td>
<td>33.46</td>
<td>6.10</td>
<td>Solugel 10336 [JJ]</td>
</tr>
</tbody>
</table>

## Schedule of Pharmaceutical Benefits

1053
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.

Coloplast dressings are available via a range of distributors. However, Coloplast’s principal agreement to ensure correct RPBS Price to Pharmacy and ready supply has been secured with Independence Australia on 1300 788 855 and BrightSky on 1300 290 400. Please note that Coloplast is unable to guarantee ready supply or rebate for price differences on purchases outside these distributors.

### DRESSING HYDROGEL AMORPHOUS

**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.

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 HYDROGEL AMORPHOUS - Dressing Hydrogel Amorphous Gel, 10 x 15 g tubes

<table>
<thead>
<tr>
<th>Max Qty Packs</th>
<th>No. of Rpts</th>
<th>Premium $</th>
<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>1</td>
<td></td>
<td>64.82</td>
<td>6.10</td>
<td>DuoDERM Gel H7990 [CC]</td>
</tr>
<tr>
<td>1</td>
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<td>72.43</td>
<td>6.10</td>
<td>Comfeel Purlion Gel 3900 [CT]</td>
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### DRESSING HYDROGEL AMORPHOUS - Dressing Hydrogel Amorphous Gel, 25 g

<table>
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<th>DPMQ $</th>
<th>MRVSN $</th>
<th>Brand Name and Manufacturer</th>
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<tr>
<td>4</td>
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<td>69.52</td>
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<td>Intrasite Gel 7313 [SN]</td>
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### DRESSING HYDROGEL AMORPHOUS - Dressing Hydrogel Amorphous Gel, 50 g

<table>
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<th>DPMQ $</th>
<th>MRVSN $</th>
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<tbody>
<tr>
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<td>31.57</td>
<td>6.10</td>
<td>SoloSite Gel 36361338 [SN]</td>
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</table>

### DRESSING HYDROGEL FOAM

### DRESSING HYDROGEL RIBBON

### 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.

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.
# Schedule of Pharmaceutical Benefits

## DRESSING NON ADHERENT

### dressing non adherent 5 cm x 7.5 cm dressing, 10

<table>
<thead>
<tr>
<th>Max Qty</th>
<th>Pack No</th>
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<td>6.10</td>
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<td>Telfa 1970C [KE]</td>
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### dressing non adherent 7.5 cm x 10 cm self adhesive dressing, 6

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### dressing non adherent 7.5 cm x 10 cm self adhesive dressing, 6

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<td>†1</td>
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## DRESSING NON ADHERENT

### DRESSING SELF ADHESIVE NON-ADHERENT DRY ABSORBENT Dressings, non-woven, with silicone 5 cm x 7.5 cm, 10

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<tr>
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</thead>
<tbody>
<tr>
<td>†1</td>
<td>..</td>
<td>..</td>
<td>63.96</td>
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<td>Mepitel 290510 [MH]</td>
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### DRESSING SELF ADHESIVE NON-ADHERENT DRY ABSORBENT Dressings, non-woven, with silicone 7.5 cm x 10 cm, 10

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<td>107.96</td>
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<td>Mepitel 290710 [MH]</td>
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## DRESSING NON ADHERENT

### 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.

### dressing non adherent 7.5 cm x 10 cm dressing, 10

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<td>†1</td>
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<td>..</td>
<td>15.58</td>
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<td>Atrauman 499513 [HR]</td>
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## DRESSING NON ADHERENT

### Note

Molnlycke Healthcare products are distributed through leading pharmacy distributors. To best ensure product availability at RPBS agreed prices, special arrangements have been made with API and Independence Australia Health Solutions (IAHS). IAHS orders can be placed on: Tel: 1300 788 855; or Email customerservice@independenceaustralia.com. Molnlycke Healthcare are not able to ensure product availability or pricing on listed products beyond these two suppliers.

### dressing non adherent 10 cm x 10 cm dressing, 10

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### dressing non adherent 10 cm x 10 cm dressing, 5

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### dressing non adherent 5 cm x 5 cm dressing, 5

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<tr>
<td>2</td>
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<td>..</td>
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## DRESSING TULLE NON GAUZE PARAFFIN

**dressing tulle non gauze paraffin 7.6 cm x 7.6 cm dressing, 1**

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</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.

**dressing with silver 10 cm x 10 cm dressing: hydroactive, 5 dressings**

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**dressing with silver 12.5 cm x 12.5 cm dressing: hydroactive, 5 dressings**

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## DRESSING WITH SILVER

**Authority required**

For wounds where there is evidence of critical colonisation and for well-assessed chronic wounds that have not responded to conventional dressings

**Note**

Hartmann wound dressings are available through HARTMANN and Independence Australia only. If you would like to order Hartmann Wound Care products, please call HARTMANN customer service on 1800 805 839 or Independence Australia on 1300 788 855.

**dressing with silver 10 cm x 10 cm dressing: tulle, 3 dressings**

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## GAUZE AND COTTON TISSUE COMBINE ROLL

**gauze and cotton tissue combine roll 10 cm x 10 m roll: wrapped pack, 1 pack**

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## 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.

**gauze and cotton tissue combine roll 9 cm x 10 m roll: wrapped pack, 1 pack**

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## TAPE NON WOVEN RETENTION POLYACRYLATE

**tape non woven retention polyacrylate 2.5 cm x 9.1 m tape, 1 roll**

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</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.

### 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.

### 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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<td>Leukoplast 01073-00 [BV]</td>
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<td>Nexcare Gentle Paper First Aid Tape 789 [MM]</td>
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<td>Leukopor 2471 [BV]</td>
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<td>Leukosilk 1021 [BV]</td>
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<td>Leukoflex 1124 [BV]</td>
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### TAPE PLASTER ADHESIVE WITH SILICONE

**Note**

Molnlycke Healthcare products are distributed through leading pharmacy distributors. To best ensure product availability at RPBS agreed prices, special arrangements have been made with API and Independence Australia Health Solutions (IAHS). IAHS orders can be placed on: Tel: 1300 788 855; or Email customerservice@independenceaustralia.com. Molnlycke Healthcare are not able to ensure product availability or pricing on listed products beyond these two suppliers.

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<td>Tape plaster adhesive hypoallergenic 5 cm x 5 m stretch tape, 1 roll</td>
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<td>Tape plaster adhesive with silicone 2 cm x 3 m tape, 1 roll</td>
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<td>Tape plaster adhesive with silicone 4 cm x 1.5 m tape, 1 roll</td>
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